PATIENT GROUP DIRECTION for the Supply of:

Varenicline (Champix®) tablets

By: Accredited Pharmacists

In: Community Pharmacies in [insert area] accredited by [insert council]

- 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
- This PGD should be reviewed every 2 years, or sooner, in light of any new guidance or information
- 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 the Client's suitability against the PGD Inclusion and Exclusion criteria and the SPC Indications/Contraindications. Client's falling outside of these criteria cannot receive varenicline under the PGD.

PGD Review date: [insert date]

[Insert Overview of amendments made at each PGD review]

1. Purpose of the PGD		
For accredited pharmacists 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 within a pharmacy contracted to provide stop smoking services or may be referred to an accredited pharmacist by a [insert council] contracted local Stop Smoking Service.		
2. Clinical condition or situation to which this PGD applies		
2.1	Define condition/ situation	Varenicline as an option for clients wishing to quit smoking and who are being monitored in the pharmacy
2.2	Criteria for inclusion	• Clients over 18 years of age • Dependant tobacco users identified as sufficiently motivated to quit • Tobacco users who are receiving support to stop smoking with a [insert council] 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 and Criteria for cautions). Refer to Appendix 1 for *Assessment to Supply Varenicline*
2.3	Criteria for exclusion	• Tobacco users not sufficiently motivated to quit or to use varenicline • Clients under 18 years of age • Sensitivity to varenicline or any of its excipients • Pregnancy/ breastfeeding • Client already receiving varenicline prescribed by GP • End stage renal disease • Epilepsy or history of fits or seizures or conditions where the seizure threshold may be lowered • Clients who have experienced serious or worrying side effects from a previous course of varenicline

2.4	Criteria for cautions [to include consideration of concurrent medication]	**Renal impairment** • No dosage adjustment is necessary for clients with mild to moderate renal impairment. For clients with moderate renal impairment who experience adverse reactions that are not tolerable, dosing may be reduced to 1 mg once daily. • For clients with severe renal impairment the recommended dose of CHAMPIX is 1 mg once daily. Dosing should begin at 0.5 mg once daily for the first 3 days then increased to 1 mg once daily. • Based on insufficient clinical experience with CHAMPIX in clients with end stage renal disease, treatment is not recommended in this Client population **Neuropsychiatric Symptoms** • The EAGLES study (April 2016) has provided evidence that the use of varenicline in clients with or without a history of psychiatric disorder was not associated with a significantly increased risk of serious neuropsychiatric adverse events compared with placebo. **Patients with History of Psychiatric Disorders** • **Smoking cessation**, **with or *without*** pharmacotherapy, has been associated with the exacerbation of underlying psychiatric illness (e.g. depression). Care should be taken with clients with a history of psychiatric illness. If this is a consideration, community pharmacists should liaise with the clients GP or mental health team prior to smoking cessation. **Effect of Smoking Cessation:** • 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. • If a client is a diabetic or is taking theophylline/aminophylline, warfarin or antipsychotic medication e.g. Clozapine ensure their GP and treating physician is notified of their quit attempt/use of varenicline using the letter provided with this PGD. (see appendix 3) - When the client stops smoking, metabolism of theophylline is reduced which could cause plasma theophylline levels to rise, possibly to toxic levels if the dose of theophylline is not adjusted. Signs of theophylline toxicity are: - vomiting, dilated pupils, sinus tachycardia and hyperglycaemia - Clients on Warfarin, should advise the clinic of their intention to quit smoking using varenicline when they next attend for a blood test - Clients taking Antipsychotics (and other medications effected by smoking cessation) should advise their treating physician of their intention to stop smoking prior to quitting

		- Clients on insulin may be supplied with varenicline. However they should be advised to monitor their blood glucose levels closely **Please note:** The above list of medications is not exhaustive and further clarification using relevant reference sources, cross referencing the client's current medication profile, should be made by the pharmacist supplying any smoking cessation product.
2.5	Client consent [verbal, written, implied]	Informed consent as stated in the local consent policy, including consent to the use of the PGD, and inform GP and/or other treating physician of supply of varenicline
2.6	Action if client excluded	Pharmacists providing [insert council] contracted Stop Smoking Services should offer clients the option of NRT or refer the client to their GP (see Appendix 2). This might include any of the conditions referred to as exclusion criteria above, but also previously unrecognised co-morbidities. Other pharmacists should direct the client back to their original [insert council] contracted Stop Smoking Service Provider. Document action in client's medication record (PMR) and smoking cessation monitoring form.
2.7	Action if treatment declined by client	Pharmacists providing [insert council] contracted Stop Smoking Services should offer other available smoking cessation options if appropriate. Other pharmacists should direct the client back to their original [insert council] contracted Stop Smoking Service Provider. 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 registered with General Pharmaceutical Council, working within and for a pharmacy with an agreement with [insert council] to provide varenicline under PGD. Must have completed the [insert detail] varenicline training programme. This PGD will only apply whilst the pharmacist is employed or contracted/working at the time in an accredited Pharmacy within [insert local details].
3.2	Additional requirements/ specialist qualifications required	Pharmacist has undertaken appropriate training to carry out clinical assessment of clients to provide most effective and safe option according to the indications listed in this PGD. 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 (Champix®) 0.5mg and 1mg tablets
4.2	Legal status POM/P/GSL	POM
	Licensed or unlicensed use [If unlicensed state rationale for use]	Licensed
4.3	Dose [Where a range is applicable include criteria for deciding on a dose]	In all circumstances dosing should follow the recommendations in the varenicline Summary of Product Characteristics: http://www.medicines.org.uk/emc **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 (normally 12 weeks in total):** 1 mg (light blue tablets) twice daily Note: The quit date is often on day 8 of taking varenicline Clients 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) **Dose tapering** In clients with a high risk of relapse, dose tapering may be considered at the end of the standard 12 weeks of treatment **Lower dose to end of treatment (normally 12 weeks in total):** 0.5 mg (white tablets) twice daily **Extending course to reduce risk of relapse:** The normal 12-week course can be repeated in abstinent individuals to reduce risk of relapse
4.4	Route / method of administration	Oral
4.5	Frequency	Once daily for the first three days, then twice daily thereafter
4.6	Total dose and number of times treatment	• 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 weekly for at least 4 weeks after the

	can be administered; state time frame	quit date, then fortnightly • Only 14-day prescription packs, supplied complete with Client Information leaflet, should be used throughout the quit attempt. • The normal treatment course is 12 weeks • An additional course of 12 weeks treatment with varenicline 1 mg twice daily may be considered • The maximum length of treatment is 24 weeks
4.7	Information on follow-up management	Advise to seek medical advice if more severe reactions to medication occur
4.8	Written/verbal advice for client before/after treatment and management	• Advice to clients should include specific product advice on dosage, method of administration and side effects. • Clients should be advised to set a quit date 7 to 14 days after initiation and advised regarding follow up and obtaining further supplies • Advise to monitor for side effects that may effect driving or using machinery • General smoking cessation advice should also be given, particularly with regard to withdrawal symptoms • The major reasons for varenicline failure are: - Unrealistic expectations - Lack of preparation for the fact that the tablets may cause nausea - Insufficient or incorrect use • It is important to make sure that the client understands the following points: 1. Varenicline is an effective medication but effort and determination are also necessary 2. It works by acting on the parts of the brain which are affected by nicotine in cigarettes 3. It does not remove all temptation to smoke or all nicotine withdrawal symptoms, but it does make abstinence easier ('it takes the edge off the discomfort') 4. 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 most clients tolerate it without problems. 5. 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 6. If client experiences any extreme side effects they should seek medical advice immediately • 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

		should inform the client accordingly and discuss or consider the need for dose tapering • No clinically significant drug interactions have been reported
4.9	Communication with client's General Practitioner	In every case when the initial supply of varenicline is made in accordance with this PGD, the pharmacist must inform the client's General Practitioner of the supply within two working days. This applies whether the pharmacy is a [insert council] contracted Stop Smoking Service Provider or not.
4.10	Communication with client's [insert council] contracted Stop Smoking Service Provider	Where the pharmacy is not the client's [insert council] contracted Stop Smoking Service Provider, the pharmacist should also inform the Service Provider within two working days of the initial supply.
4.11	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. Clients should also be asked at every appointment about nicotine withdrawal symptoms, including mood changes. **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. Clinicians should be aware of the possible emergence of serious neuropsychiatric symptoms in clients attempting to quit smoking **with or without** treatment. If serious neuropsychiatric symptoms occur clients should be advised to discontinue treatment and seek prompt medical advice. 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 [insert council] contracted Stop Smoking Service Provider, the pharmacist should also inform the Service Provider. 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/
4.12	Arrangements for referral for medical advice	Pharmacist 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).
4.13	Precautions, facilities & supplies	Store in a cool dry place. Order supplies from licensed pharmacy wholesalers.

4.14	Specify method of recording supply sufficient to enable audit trail	Client notes (Manual, Computerised, Client Held): • Client's name, address, date of birth and GP details. • Referring [insert council] contracted Stop Smoking Service Provider. • Date supplied and name of the pharmacist who supplied the medication. • Batch number and expiry date. • 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	PGD group	[Insert name, job title and organisation of PGD group members]
6.2	Authorisation This PGD has been approved on behalf of [insert council] by: [complete boxes below as per local requirements]	

Job title	Name	Signature	Date

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

Service Specification
Current edition of the British National Formulary
Manufacturer's Summary of Product Characteristics

PGD for administration of varenicline tablets by Community Pharmacists within [insert area]

- **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.

- **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 of Healthcare Professional (Pharmacist)	Signature	Authorised Person with responsibility for PGDs: Commissioning Manager or Deputy	Signature	Date approved

Appendix 1

Pharmacist's Clinical Assessment to Supply Varenicline (Champix®)

Client Name _____ DOB _____

Client Address _____

_____

Name of referring [insert council] contracted Stop Smoking Service Provider (if applicable)

_____

Is the client sufficiently motivated to stop smoking?

If no, DO NOT continue with this form or supply varenicline - advise the client to return when they are ready to make a quit attempt.

Is the client taking any other medication? *Client's taking medications that may be affected when they stop smoking should be advised to tell their treating physician of their quit attempt.*

Yes No

Please list:

Criteria for Exclusion

Is the client sensitive to varenicline tartrate or any of its excipients?	**Yes**	**No**
Is the client under 18 years old?		
Does the client have end-stage renal disease?		
Is the client pregnant?		
Is the client breastfeeding?		
Does the client have epilepsy or history of fits or seizures or conditions where the seizure threshold may be lowered?		
Does the Client have a history of serious psychiatric illness? (If yes, consider referring to GP, CPN or psychiatrist for discussion)		

If the client answers yes to any of the above then varenicline may not be suitable. Other options available to the client are:

- direct client back to the referrer for consideration of other treatments, if applicable
- offer the option of NRT (if a WCC Contracted Stop Smoking Service Provider)
- refer client to their GP using the Notification Form in Appendix 2

If in doubt seek further advice from the client's GP

Name of Pharmacist: **Date:**

Signature:

Appendix 2

Pharmacist referral to GP: patients excluded from varenicline PGD

URGENT & CONFIDENTIAL FAX

Data protection confidentiality note: this message is intended only for the use of the individual or entity to whom it is addressed and may contain information that is privileged, confidential and exempt from disclosure under law. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited.	Pharmacy Stamp

FAO: GP Name_____

GP Address_____

Notification of consultation and non-supply of varenicline

Client's Name _____

Address _____

_____

DOB _____ Telephone_____

Dear Doctor

A consultation has taken place with your patient in accordance with the [insert council] varenicline Patient Group Direction to assess whether it is appropriate for them to receive varenicline. However, no supply under the PGD has been made, due to the following being identified:

(Summarise here details from assessment form (Appendix 1))

CONSENT

I,_____ (client name) confirm that the above information has been discussed with me and is an accurate record of that discussion.

I give my consent to the above information to be passed to my GP.

Signature:_____ Date:_____

Appendix 3

Pharmacist Notification to GP/Treating Physician of supply of varenicline

URGENT & CONFIDENTIAL FAX

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Pharmacy Stamp

FAO: GP Name_____

GP Address_____

Notification of supply of varenicline

Client's Name _____

Address ` _____

_____

DOB _____ Telephone_____

Dear Doctor

I write to advise you that your patient has been seen by me for smoking cessation treatment. They have expressed a wish to use varenicline to aid their effort in stopping smoking, and a medical history has taken place to assess whether it is appropriate for them to receive it. I have ascertained that your patient does not have any contraindications, or risk factors, for taking varenicline and meets the criteria for a supply to be made under the local Patient Group Direction. If you have any concerns about this person commencing varenicline then please do not hesitate to contact me.

Name: _____ Phone No: _____

Signature: _____Date: _____

Client is receiving varenicline from this pharmacy:

Name of Pharmacy: _____

Address: _____

Name of Stop Smoking Service (if different) _____

Address: _____

Please note medical records may need updating if there is a change in the patient's smoking status – remember to Read code.