

**PATIENT GROUP DIRECTION for the Supply of:**

**Varenicline▼ (Champix®) tablets**

**By: Accredited Pharmacists**

**In: Community Pharmacies in Calderdale 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: 1<sup>st</sup> November 2023

**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 by Yorkshire Smokefree or may be referred to an accredited pharmacist by Yorkshire Smokefree 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	<ul style="list-style-type: none"> <li>• Clients over 18 years of age</li> <li>• Tobacco users identified as sufficiently motivated to quit</li> <li>• Tobacco users who are receiving support to stop smoking with Yorkshire Smokefree or a Yorkshire Smokefree contracted Stop Smoking Service</li> <li>• 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 1 for <i>Varenicline voucher</i></li> </ul>
2.3	Criteria for exclusion	<ul style="list-style-type: none"> <li>• Tobacco users not sufficiently motivated to quit or to use varenicline</li> <li>• Clients under 18 years of age</li> <li>• Sensitivity to varenicline or any of its excipients</li> <li>• Pregnancy/ breastfeeding</li> <li>• Client already receiving varenicline prescribed by GP</li> <li>• End stage renal disease as decreased clearance by kidney increases side effects</li> <li>• Epilepsy or history of fits or seizures</li> <li>• Clients who have experienced serious or worrying side effects from a previous course of varenicline</li> <li>• Patients with a history of serious psychiatric illness such as schizophrenia, bipolar disorder or major depressive illness</li> </ul>
2.4	Criteria for cautions [to include consideration of Concurrent medication]	<p><b>Renal impairment</b></p> <ul style="list-style-type: none"> <li>• No dosage adjustment is necessary for clients with mild to moderate renal impairment. For clients who disclose moderate or severe renal impairment dosing may be reduced to 1 mg once daily.</li> <li>• Based on insufficient clinical experience with CHAMPIX in clients with end stage renal disease, treatment is not recommended in this Client population</li> </ul>

		<p><b>Neuropsychiatric Symptoms</b></p> <ul style="list-style-type: none"> <li>• 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.</li> </ul> <p><b>Patients with History of Psychiatric Disorders</b></p> <ul style="list-style-type: none"> <li>• <b>Smoking cessation, with or without</b> 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. .</li> </ul> <p><b>Effect of Smoking Cessation:</b></p> <ul style="list-style-type: none"> <li>• 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, <b>with or without</b> treatment with varenicline, may alter the pharmacokinetics or pharmacodynamics of some medicinal products for which dose adjustment may be necessary.</li> <li>• If a client is a diabetic or is taking theophylline/aminophylline, warfarin or antipsychotic medication e.g.             <ul style="list-style-type: none"> <li>- 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</li> <li>- Clients on Warfarin, should advise the clinic of their intention to quit smoking using varenicline when they next attend for a blood test</li> <li>-</li> <li>- Clients on insulin may be supplied with varenicline. However they should be advised to monitor their blood glucose levels closely</li> </ul> </li> </ul> <p><b>Please note:</b> The above list of medications is not exhaustive and further clarification using relevant reference sources, cross referencing</p>
--	--	--

		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 informing GP of supply of varenicline
2.6	Action if client excluded	Pharmacists 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 pharmacists should direct the client back to Yorkshire Smokefree. Document action in client's medication record (PMR) and inform service provider of the outcome'
2.7	Action if treatment declined by client	Pharmacists providing Yorkshire Smokefree contracted Stop Smoking Services should offer other available smoking cessation options if appropriate. Other pharmacists should direct the client back to Yorkshire Smokefree.  Document action in client's medication record (PMR) and inform the Service Provider of the outcome
<b>3. Characteristics of staff</b>		
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 Yorkshire Smokefree to provide varenicline under PGD.  It is the responsibility of the individual pharmacist to ensure that they and their staff are competent in all aspects of supply of Varenicline.  This PGD will only apply whilst the pharmacist is employed or contracted/working at the time in an accredited Pharmacy within Calderdale
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.
<b>4. Description of treatment</b>		
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]	<p><b>Days 1 – 3:</b> 0.5 mg (white tablets) once daily</p> <p><b>Days 4 – 7:</b> 0.5 mg twice daily</p> <p><b>Day 8 to the end of treatment (up to a maximum of 12 weeks):</b> 1 mg (light blue tablets) twice daily</p> <p>Note: The quit date is often on day 8 of taking Varenicline.</p> <p>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). The 0.5mg dose must be supplied in the 56 tablet pack.</p> <p><b>Lower dose to end of treatment (up to 12 weeks in total):</b> 0.5 mg (white tablets) twice daily</p> <p>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</p> <p>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.</p>
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 can be administered; state time frame	<ul style="list-style-type: none"> <li>• Clients should be supplied a 14 day initiation pack and should set a quit date 7 to 14 days after initiation</li> <li>• Clients should be seen by the stop smoking Advisor, weekly for at least 4 weeks after the quit date, then fortnightly.</li> <li>• Clients should be seen by the pharmacist at each supply of Varenicline</li> <li>• Only 14-day or 28-day (for 0.5mg dose only) prescription packs should be used throughout the quit attempt</li> <li>• The treatment course is up to 12 weeks</li> </ul>
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	<ul style="list-style-type: none"> <li>• Clients should be advised to set a quit date 7 to 14 days after initiation</li> <li>• The major reasons for varenicline failure are: <ul style="list-style-type: none"> <li>- Unrealistic expectations</li> <li>- Unable to tolerate side-effect of nausea</li> <li>- Insufficient or incorrect use</li> </ul> </li> <li>• It is important to make sure that the client understands the following points: <ol style="list-style-type: none"> <li>1. Varenicline is an effective medication but effort and determination are also necessary</li> <li>2. It works by acting on the parts of the brain which are affected by nicotine in cigarettes</li> <li>3. It does not remove all temptation to smoke, but it does make abstinence easier</li> <li>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 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.</li> <li>5. Instruct on correct use and daily dose. Use mock product packaging for the</li> </ol> </li> </ul>

		<p>explanation. Clients should take varenicline for 7 to 14 days before stopping smoking</p> <ul style="list-style-type: none"> <li>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</li> <li>No clinically significant drug interactions have been reported</li> </ul>
4.9	Communication with client's General Practitioner	<p>In every case when a supply of varenicline is made in accordance with this PGD, the pharmacist must inform the client's General Practitioner (GP) of the supply in a timely manner, by sending the GP copy of the voucher to the clients GP where a paper voucher has been used. Where an electronic voucher has been issued, the pharmacist should inform the client's GP using either 'Notification of first, or further supply of Varenicline through the PGD' (Appendix 1 and 2).. This must not exceed one calendar month. This applies whether the pharmacy is a Yorkshire Smokefree contracted Stop Smoking Service Provider or not.</p>
4.11	Instructions on identifying, managing & reporting adverse drug reactions	<p>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.</p> <p>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 CHAMPIX studies to distinguish between adverse events associated with study drug treatment or those possibly associated with nicotine withdrawal.</p>

		<p>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 should also inform the Service Provider.</p> <p>If the client, family or care givers have concerns about agitation, depressed mood or changes in behaviour varenicline should be stopped immediately.</p> <p>Please refer to current BNF and SPC for full details.</p> <p>Report all Adverse Drug Reactions using the Yellow Card System: <a href="https://yellowcard.mhra.gov.uk/">https://yellowcard.mhra.gov.uk/</a></p>
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	<p>Store in a cool dry place.</p> <p>Order supplies from licensed pharmacy wholesalers.</p>
4.14	Specify method of recording supply sufficient to enable audit trail	<p>Pharmacists 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:</p> <ul style="list-style-type: none"> <li>• Client's name, address, date of birth and GP details.</li> <li>• Referring Yorkshire Smokefree contracted Stop Smoking Service Provider.</li> <li>• Date supplied and name of the pharmacist who supplied the medication.</li> <li>• Reason for inclusion.</li> <li>• Advice given to client.</li> <li>• Details of any adverse drug reaction and actions taken including documentation in the client's medical record via GP (as well</li> </ul>





		as reporting to the CSM using the 'Yellow Card' reporting system.	
<b>5. Audit</b>			
The use of this PGD to be monitored by the service in which it is used.			
<b>6. Management</b>			
6.1	This PGD has been written by:		
Job title	Name	Signature	Date
Deputy Chief Pharmacist	Sarah Hudson		
Pharmacist Yorkshire Smokefree	Susan Jones		
Medical Director	Subha Thiyagesh		26.10.2020
6.2	This PGD has been approved on behalf of South West Yorkshire Partnership NHS Foundation Trust and Calderdale by:		
Job title	Name	Signature	Date
Medical Director	Subha Thiyagesh		26.10.2020
6.3	Persons permitted to authorise staff they are responsible for to operate this PGD		
	Commissioning Manager for the County Council or Deputy		
<b>7. References and Sources of Information</b>			
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 Calderdale**

- **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



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

<b>Patient Name</b>	
<b>Address</b>	
<b>Date of Birth</b>	

**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 (Champix) Tablets of which I am an accredited Pharmacist.

Varenicline (Champix) 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. Renal disease		
6. Epilepsy or history of fits or seizures		
7. Sensitivity to varenicline or excipients, or serious side effects from previous course of varenicline		
8. Serious psychiatric illness e.g.schizophrenia, bipolar disorder or major depressive illness.		
<b>Clients must answer YES to Qs 1-3 to be eligible</b>  <b>If clients answer YES to any of Qs 4-8 they are NOT eligible for varenicline through the PGD</b>		

**Pharmacist Name**

**Date of supply**

**Name and Address of Pharmacy**



**Notification of FURTHER supply of Varenicline (Champix) to your patient through the Varenicline PGD**

<b>Patient Name</b>	
<b>Address</b>	
<b>Date of Birth</b>	

**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 (Champix) Tablets of which I am an accredited Pharmacist.**

Varenicline Maintenance Pack 28 x 1 mg bd	
Varenicline Maintenance Pack 56 x 0.5 mg bd	

**Supply ..... of 6**

**Pharmacist Name**

**Date of supply**



**Name and Address of Pharmacy**

