

This Patient Group Direction (PGD) must only be used by registered Pharmacists 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 should be used.

**Patient Group Direction**

For the supply of

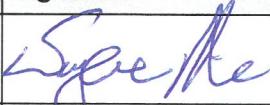
Varenicline (Champix) Tablets 0.5mg and 1mg

By registered pharmacists for

Smoking cessation

In Northumberland, North Tyneside and Newcastle

**PGD authorisation**

Name	Job title and organisation	Signature	Date
Senior doctor Eugene Milne	Director of Public Health, Newcastle City Council		14/5/15
Senior pharmacist Anne Everden	Pharmacy Consultant to PH, North Tyneside and Northumberland County Council.		29/4/15
Person signing on behalf of authorising body Karen Rowell	Public Health Service Manager, Northumberland County Council.		29/4/15.

**Version number: North of Tyne -3.V1**

**Change history**

Version number	Change details	Date
	New PGD	

Reference Number: NOT-3. Final V1

Valid from: July 2015

Review date: February 2017

Expiry date: July 2017

### Training and competency of registered Pharmacists

	<b>Requirements of registered pharmacists working under the PGD</b>
<b>Qualifications and professional registration</b>	Registered with the General Pharmaceutical Council
<b>Initial training</b>	Must attend North of Tyne approved initial training prior to using the PGD
<b>Competency assessment</b>	Pharmacists will have; <ul style="list-style-type: none"> <li>• Appropriate indemnity insurance</li> <li>• Systems to protect confidential information</li> </ul>
<b>Ongoing training and competency</b>	<ul style="list-style-type: none"> <li>• Maintain knowledge and expertise and keep up to date with any changes in smoking cessation through professional CPD</li> <li>• Complete annual refresher training as appropriate</li> </ul> <p>This PGD will only apply whilst the pharmacist is commissioned to provide varenicline by a North of Tyne local authority as part of the smoking cessation service.</p>

### Clinical condition

<b>Clinical condition or situation to which this PGD applies</b>	Clients accessing the pharmacy based smoking cessation service, as one of the treatment options of the smoking cessation programme
<b>Inclusion criteria</b>	<ul style="list-style-type: none"> <li>• Clients 18 years of age and over</li> <li>• Nicotine users identified as sufficiently motivated to quit</li> <li>• Nicotine users who are receiving support to stop smoking with a North of Tyne contracted NHS Stop Smoking Service</li> <li>• Client is resident in North of Tyne or is registered with a North of Tyne GP</li> <li>• A medical history is taken and documented and there are no contraindications for treatment with varenicline and that any cautions for use are recorded. Refer to Appendix 1 for <i>Assessment to Supply Varenicline</i></li> <li>• No indication on PMR that the patient is unsuitable for Varenicline</li> </ul>
<b>PGD Exclusion criteria</b>	<ul style="list-style-type: none"> <li>• Tobacco users not sufficiently motivated to quit or 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>• Renal impairment or end stage renal disease as decreased clearance by kidney increases side effects. (Use with caution in the elderly)</li> <li>• Epilepsy or history of fits or seizures</li> <li>• Substance misuse patients</li> <li>• Clients who have experienced serious or worrying side effects from a previous course of varenicline</li> <li>• PMR indicates that patient is unsuitable for Varenicline</li> <li>• Clients with active or history of severe and enduring mental illness</li> </ul>
<b>Cautions (including any relevant action to be taken)</b>	<p>If a client has diabetes or is taking theophylline/aminophylline or warfarin, ensure their GP is notified of their quit attempt/use of varenicline using the letter provided with this PGD. (see appendix X)</p> <ul style="list-style-type: none"> <li>• Patients on insulin may be supplied with varenicline. However patients should be advised to monitor their blood glucose level closely.</li> <li>• Patients taking warfarin, should advise the clinic of their intention to quit</li> </ul>

Reference Number: NOT-3. Final V1

Valid from: July 2015

Review date: February 2017

Expiry date: July 2017

	<p>smoking using varenicline when they next attend for a blood test</p> <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> </ul>
<b>Action to be taken if patient excluded (1)</b>	<p>If the patient is excluded from the PGD, but not excluded from being prescribed varenicline i.e.</p> <ul style="list-style-type: none"> <li>History of serious and enduring psychiatric illness – schizophrenia, bipolar, major depressive disorder</li> <li>Epilepsy</li> </ul> <p>Pharmacists should refer clients to GP (Letter -Appendix 3) for clinical assessment. After clinical assessment ,the doctor may then provide a patient specific direction which will allow the pharmacist to provide the full course of varenicline in instalments</p>
<b>Action to be taken if patient excluded (2)</b>	If excluded for other reasons - Refer back to smoking cessation adviser
<b>Action to be taken if patient declines treatment</b>	Refer back to smoking cessation adviser

### Details of the medicine

Name, form and strength of medicine, include ▼ for <u>black triangle medicines</u>	Varenicline▼ (Champix®) 0.5mg tablets Varenicline▼ (Champix®) 1mg tablets
Legal category	POM Black Triangle - Subject to intensive monitoring
Indicate any <u>off-label use</u>	
Route/method of administration	Oral
Dose and frequency	<p><b>Days 1-3</b> 500 micrograms (<i>white tablets</i>) once daily</p> <p><b>Days 4-7</b> 500 micrograms twice daily</p> <p><b>Day 8 to end of treatment</b> 1mg (<i>blue tablets</i>) twice daily for 11 weeks (Reduce to 500micrograms twice daily if not tolerated)</p> <p>Maximum single dose 1mg Maximum daily dose 2mg</p> <p>Clients should set a date to stop smoking. Client should start taking varenicline 1-2 weeks before this date</p> <p>Tablets should be swallowed whole with plenty of water and can be taken with or without food</p> <p>Patients who cannot tolerate the adverse effects of varenicline may have the dose lowered temporarily or permanently to 500micrograms twice a day.</p>

Reference Number: NOT-3. Final V1

Valid from: July 2015

Review date: February 2017

Expiry date: July 2017

	<p><b>Patients who are anxious about coming off varenicline may have their dose lowered towards the end of treatment (maximum 12 weeks in total): Patients can be advised to taper their remaining tablets by taking one tablet daily for 3-4 days then one tablet every two days</b></p>
<b>Quantity to be supplied</b>	<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 (Clients should be seen weekly by their Stop Smoking Adviser for at least 4 weeks after the quit date, then fortnightly.)</li> <li>At two weeks, pharmacists should confirm that patient has quit, and that GP has not objected to patient receiving varenicline, then supply 2 weeks of varenicline.</li> <li>All further supplies will be made at two weekly intervals after confirmation from Stop Smoking adviser that client should continue on varenicline.</li> <li>Only 14-day prescription packs should be used throughout the quit attempt</li> <li>A starter pack can be used in reverse for the final two weeks if appropriate</li> </ul> <p>The normal treatment course is up to 12 weeks</p>
<b>Drug Interactions</b>	No clinically meaningful drug interactions have been reported. Since metabolism of varenicline represents less than 10% of its clearance, active substances known to affect the cytochrome P450 system are unlikely to alter the pharmacokinetics of varenicline.
<b>Side effects</b>	<ul style="list-style-type: none"> <li>Nausea</li> <li>Sleep disorders/abnormal dreams</li> <li>Headache</li> <li>Appetite changes</li> <li>Dry mouth/taste disturbances</li> <li>Drowsiness</li> <li>Dizziness</li> </ul> <p>Please refer to SPC or current BNF (<a href="http://www.bnf.org.uk">http://www.bnf.org.uk</a>) for full details      Use the Yellow Card System to report adverse drug reactions directly to the CSM.      Guidance on its use is available at the back of the BNF or can be accessed via the CSM website (<a href="http://www.yellowcard.gov.uk">http://www.yellowcard.gov.uk</a>)</p>
<b>Records to be kept</b>	<p>Complete record of consultation for smoking cessation + varenicline which includes;</p> <ul style="list-style-type: none"> <li>Patients name, date of birth, postcode and consent given</li> <li>Name and address of GP</li> <li>Varenicline assessment form</li> <li>Dose and form administered/supplied</li> <li>Batch and expiry date details</li> <li>Communications with GP</li> <li>Advice given to patient (including side effects)</li> <li>Signature of Pharmacist</li> <li>Signature of patient</li> <li>Any ADR</li> </ul> <p>Input data onto appropriate data collection system (Pharmaoutcomes/Portal)</p>

## Patient information

<b>Information to be given to patient</b>	<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> </ul> </li> </ul>
---	--

Reference Number: NOT-3. Final V1

Valid from: July 2015

Review date: February 2017

Expiry date: July 2017

	<ul style="list-style-type: none"> <li>- Lack of preparation for the fact that the tablets may cause nausea</li> <li>- Insufficient or incorrect use</li> </ul> <ul style="list-style-type: none"> <li>• It is important to make sure that the client understands the following points:           <ol style="list-style-type: none"> <li>1. Varenicline is not a magic cure - effort and determination are crucial</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 most clients tolerate it without problems. If client is unable to tolerate due to nausea , consider dose reduction</li> <li>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</li> </ol> </li> </ul> <p>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</p>
Communication with client's General Practice	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.(See appendix 2)

Reference Number: NOT-3. Final V1

Valid from: July 2015

Review date: February 2017

Expiry date: July 2017

## Appendices

### Appendix A. Key references

1. Summary of Product Characteristics (SPC) for Champix . [www.emc.medicines.org](http://www.emc.medicines.org)
2. British National Formulary
3. National Institute for Health and Clinical Excellence – Varenicline for Smoking Cessation Technology Appraisal 123 July 2007
4. Medicine and Health Product Regulatory Agency (MHRA) safety alert November 2008

### Appendix B. PGD Working Group

Name	Job title and organisation	Signature	Date
Lead author- Karen Rowell	Public Health (PH) Service Manager	Karen Rowell	16/4/15
Lead doctor - Dr Ruth Evans	Clinical Director North Tyneside CCG	Ruth Evans	6/5/15
Lead pharmacist - Anne Everden	Pharmacy Consultant to PH, North Tyneside and Northumberland County Council.	Anne Everden	16.4.15
Representative of other professional group using PGD- Ann Gunning	Community Pharmacy Development Lead, North of Tyne LPC	Ann Gunning	16/4/15
<b>Other members of the PGD working group</b>			
Kerry Lynch	Public Health Specialist Northumberland County Council	Kerry Lynch	29.4.15
Wendy Burke	Acting Director of Public Health North Tyneside Council	Wendy Burke	16/4/15
Lynda Seery	Public Health Specialist/ Commissioner Newcastle City Council	Lynda Seery	20/4/15
Brenda Warner	Stop Smoking Service Manager Northumbria Healthcare NHS Foundation Trust	Brenda Warner	4/6/15
David Fellows	Public Health Trainer, North Tyneside Council	David Fellows	16/4/15

Reference Number: NOT-3. Final V1

Valid from: July 2015

Review date: February 2017

Expiry date: July 2017

## *Appendix C Health professionals' agreement to practise*

I have read and understood the Patient Group Direction and agree to supply and/or administer this medicine only in accordance with this PGD.

Reference Number: NOT-3, Final V1

Valid from: July 2015

Review date: February 2017

Expiry date: July 2017

## Appendix 1

### Client Assessment Form for Varenicline

As you have chosen to consider Varenicline as your medication to help stop smoking, please complete the questions below. As it has already been discussed with you, treatment with Varenicline may have side effects. This medicine may not be appropriate for you if you have certain medical conditions. If you do not want to answer a question or want to speak to a smoking advisor/pharmacist confidentially, please highlight this to the pharmacist.

If you are commenced on Varenicline a letter will be sent to your GP to inform them. They will be asked to contact us if they have any concerns with you receiving the treatment.

#### Social History

In a week how many units would you drink? ..... Units

1 Unit = half a pint, 1 unit = 125ml (small glass of wine), 1 unit = single measure of a spirit

#### Past Medical History

Do you have a history of feeling depressed, low in mood? Yes/no

Have you ever been diagnosed with bipolar disorder? Yes/No

Have you ever been prescribed medication for low mood, depressions or anxiety?

E.g. antidepressants Yes/No

Have you ever been diagnosed with a seizure (fits) disorder? Yes/No

Have you ever been diagnosed with an eating disorder? Yes/No

#### Current Medical History

During the last month, have you often been bothered by feeling down, depressed or hopeless? Yes/No

During the last month have you often been bothered by having little interest or pleasure in doing things Yes/No

Do you have reduced kidney function? (also called renal impairment) Yes/No

#### Medical History

Please provide a list of your current medications to the advisor for information (this will be documented in your management plan). Please include medicines that you buy from a pharmacy plus any herbal products or vitamins you are taking.

.....

.....

.....

Patient Name (please print) .....

Signature ..... Date .....

I confirm that the information provided is a true reflection and allows the Community Pharmacist to provide the most appropriate, most safe advice and treatment for me.

## Appendix 2

### **Notification to General Practitioners of supply of varenicline by community pharmacist**

Date

Pharmacy Stamp

GP Name

GP Address

Pharmacy telephone or email

Dear Doctor

**MEDICATION BEGUN: Varenicline 0.5mg daily from (date.....) to be prescribed by pharmacist**

I am writing to inform you that

Patient Name

Date of Birth

Address

NB	Patient on	
	Insulin	
	Warfarin	
	Theophylline	

has been prescribed varenicline as an adjunct to their quit attempt. The client will be supplied varenicline for up to 12 weeks, and the dose will be increased stepwise to 1mg twice daily at day 8.

If there is information within the patient's medical record which would mean that varenicline is contraindicated in this patient please inform me at the telephone number above within the next 48hours.

Client declaration: I agree to the pharmacy passing on this information to my GP in order to ensure that my medical records are up to date.

Patient Signature

Date

Pharmacist Signature

FOR General Practice Use Only

Name of Patient

Date of Birth

I have considered the risks and benefits of using varenicline in this patient and consider they **ARE NOT SUITABLE** for varenicline treatment

Signed

Print Name

Date

**Appendix 3 (part 1)**

**Referral to General Practitioners for Assessment of client's clinical suitability for supply of varenicline by community pharmacist**

Date

Pharmacy Stamp

GP Name

GP Address

Pharmacy fax or email address

Dear Doctor

The following client

Name

Date of Birth

Address

has registered with the smoking cessation service, and wishes to use varenicline as part of their quit attempt. The client has stated that they have a previous history of

- Epilepsy
- Serious and enduring psychiatric illness
- Serious and enduring depressive illness

Please could you review their suitability for this medication and inform the above pharmacy within 48 hours using the slip provided. If the patient is deemed suitable, this will form the basis of a patient specific direction which will allow the pharmacist to provide the 12 week course of varenicline in instalments.

Client declaration: I agree to the pharmacy passing on this information to my GP in order to determine my clinical suitability to receive varenicline.

Patient Signature

Date

Pharmacist signature

Date

---

## Appendix 3 (Part 2)

---

### FOR General Practice Use Only

Note to General practitioner – please complete and sign this form indicating whether or not the patient is suitable for varenicline within 48 hours and return it to the community pharmacy above.

Name of Patient

Date of Birth

Address

I have considered the risks and benefits of using varenicline in this patient and  
consider they **ARE NOT SUITABLE** for varenicline treatment

I have considered the risks and benefits of using varenicline in this patient and  
consider they **ARE SUITABLE** for varenicline treatment

Signature of doctor

Print Name

Date

**This document is a patient specific direction authorising**

community pharmacy .....

address .....

to supply one course of varenicline in instalments to the above named patient.

Signature of doctor

Print Name

Date

Note to pharmacist – please ask the patient to deliver this form to the surgery where they are registered as a patient.

## Appendix 4

### Checklist for pharmacist supply of varenicline on Patient Group Direction

Name Smoking Cessation Adviser

Date of Birth Name

Address Tele:

1. Patient has been assessed by smoking cessation adviser

2. Patient assessment form completed (appendix1)  
(including patient signature)

3. Patient's GP informed of supply

4. No response from GP advising against supply

5. Patient does not meet PGD criteria

6. Referral sent to GP ...please insert date

7. Response received from GP please insert date

8. Signed Patient Specific direction received

9. Supplies made

	Notification received from stop smoking adviser	Date of supply	Initials of pharmacist
1			
2			
3			
4			
5			
6			

**Appendix 5**

**Referral to General Practitioners for Housebound Patients  
requiring varenicline**

Date

Pharmacy Stamp

GP Name

GP Address

Pharmacy fax or email address

Dear Doctor

The following client

Name

Date of Birth

Address

has registered with the smoking cessation service, and wishes to use varenicline as part of their quit attempt. The client is housebound, and therefore cannot be assessed in person by the community pharmacist. However, the trained Stop Smoking adviser will support their quit attempt in the home.

Please could you review their suitability for this medication and inform the above pharmacy within 48 hours using the slip provided. If the patient is deemed suitable, this will form the basis of a patient specific direction which will allow the pharmacist to provide the 12 week course of varenicline in instalments.

Pharmacist signature

Date

Stop Smoking Adviser Name

Address

Voucher Number

---

## Appendix 5 (Part 2)

---

### FOR General Practice Use Only - Housebound Patient

Note to General practitioner – please complete and sign this form indicating whether or not the patient is suitable for varenicline within 48 hours and return it to the community pharmacy above.

Name of Patient

Date of Birth

Address

I have considered the risks and benefits of using varenicline in this patient and  
consider they **ARE NOT SUITABLE** for varenicline treatment

I have considered the risks and benefits of using varenicline in this patient and  
consider they **ARE SUITABLE** for varenicline treatment

I understand that support to Stop Smoking will be provided by a trained adviser in the home.

Signature of doctor

Print Name

Date

**This document is a patient specific direction authorising**

community pharmacy .....

address .....

to supply one course of varenicline in instalments to the above named patient.

Signature of doctor

Print Name

Date

Voucher No