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

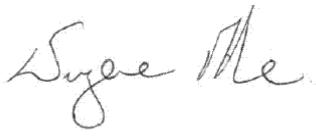
Varenicline (Champix) Tablets 0.5mg and 1mg

By registered pharmacists for

Smoking cessation

In North Tyneside and Newcastle

## PGD authorisation

| Name | Job title and organisation | Signature | Date |
|---|---|---|---|
| **Senior doctor**<br>Eugene Milne | Director of Public Health, Newcastle City Council |  | 03/09/19 |
| **Senior pharmacist**<br>Andre Yeung | Senior Specialist Advisor, Newcastle City Council |  | 03/09/19 |
| **Person signing on behalf of authorising body**<br>Lynda Seery | Public Health Specialist, Newcastle City Council. |  | 03/09/19 |

**Version number: NCCNTv1.1**

**Change history**

| Version number | Change details | Date |
|---|---|---|
| 2017 Version | New signatures & removal of Northumberland Council | 17/08/17 |
| 2019 Version | New signatures & review against latest BNF | 03/09/19 |
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| PGD Development Group, see Appendix B |
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**Training and competency of registered Pharmacists**

| | Requirements of registered pharmacists working under the PGD |
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| **Qualifications and professional registration** | Registered with the General Pharmaceutical Council |
| **Initial training** | Must have undertaken approved initial training prior to using the PGD |
| **Competency assessment** | Pharmacists will have;<br>• Appropriate indemnity insurance<br>• Systems to protect confidential information |
| **Ongoing training and competency** | • Maintain knowledge and expertise and keep up to date with any changes in smoking cessation through professional CPD<br>• Complete annual refresher training as appropriate<br>This PGD will only apply whilst the pharmacist is commissioned to provide varenicline by a Newcastle or North Tyneside local authority as part of the smoking cessation service. |

## Clinical condition

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| **Clinical condition or situation to which this PGD applies** | Clients accessing the pharmacy based smoking cessation service, as one of the treatment options of the smoking cessation programme |
| **Inclusion criteria** | • Clients 18 years of age and over<br>• Nicotine users identified as sufficiently motivated to quit<br>• Nicotine users who are receiving support to stop smoking with a Newcastle or North Tyneside contracted NHS Stop Smoking Service<br>• Client is resident in Newcastle or North Tyneside or is registered with a Newcastle or North Tyneside GP<br>• 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 *Assessment to Supply Varenicline*<br>• No indication on PMR that the patient is unsuitable for Varenicline |
| **PGD Exclusion criteria** | • Tobacco users not sufficiently motivated to quit or use varenicline<br>• Clients under 18 years of age<br>• Sensitivity to varenicline or any of its excipients<br>• Pregnancy/ Breastfeeding<br>• Client already receiving varenicline prescribed by GP<br>• History of cardiovascular disease<br>• Renal impairment or end stage renal disease as decreased clearance by kidney increases side effects. (Use with caution in the elderly)<br>• Epilepsy or history of fits or seizures<br>• Substance misuse patients<br>• Clients who have experienced serious or worrying side effects from a previous course of varenicline<br>• PMR indicates that patient is unsuitable for Varenicline<br>• Clients with active or history of severe and enduring mental illness |
| **Cautions (including any relevant action to be taken)** | • 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 2) |

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| | • Patients on insulin may be supplied with varenicline. However, patients should be advised to monitor their blood glucose level closely.<br>• Patients taking warfarin, should advise the clinic of their intention to quit smoking using varenicline when they next attend for a blood test<br>• 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<br>• Patients should be advised to discontinue treatment and seek prompt medical advice if they develop agitation, depressed mood or suicidal thoughts. |
| **Action to be taken if patient excluded (1)** | If the patient is excluded from the PGD, but not excluded from being prescribed varenicline i.e.<br>• History of serious and enduring psychiatric illness – schizophrenia, bipolar, major depressive disorder<br>• Epilepsy<br>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 |
| **Action to be taken if patient excluded (2)** | If excluded for other reasons - Refer back to smoking cessation adviser |
| **Action to be taken if patient declines treatment** | Refer back to smoking cessation adviser |

## Details of the medicine

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| **Name, form and strength of medicine** | Varenicline (Champix®) 0.5mg tablets<br>Varenicline (Champix®) 1mg tablets |
| **Legal category** | POM |
| **Indicate any off-label use** | |
| **Route/method of administration** | Oral |
| **Dose and frequency** | **Days 1-3**<br>500 micrograms (*white tablets*) once daily<br><br>**Days 4-7**<br>500 micrograms twice daily for 4 days<br><br>**Day 8 to end of treatment**<br>1mg (*blue tablets*) twice daily for 11 weeks<br>(Reduce to 500micrograms twice daily if not tolerated)<br><br>Maximum single dose 1mg<br>Maximum daily dose 2mg |

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| | Clients should set a date to stop smoking. Client should start taking varenicline 1-2 weeks before this date<br><br>Tablets should be swallowed whole with plenty of water and can be taken with or without food<br><br>Patients who cannot tolerate the adverse effects of varenicline may have the dose lowered temporarily or permanently to 500micrograms twice a day.<br><br>**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** |
| **Quantity to be supplied** | • 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).<br>• 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.<br>• All further supplies will be made at two weekly intervals after confirmation from Stop Smoking adviser that client should continue on varenicline.<br>• Only 14-day prescription packs should be used throughout the quit attempt.<br>• A starter pack can be used in reverse for the final two weeks if appropriate.<br>• The normal treatment course is up to 12 weeks. |
| **Drug Interactions** | 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. |
| **Side effects** | • Nausea<br>• Sleep disorders/abnormal dreams<br>• Headache<br>• Appetite changes<br>• Dry mouth/taste disturbances<br>• Drowsiness<br>• Dizziness<br>Please refer to SPC or current BNF (http://www.bnf.org.uk) for full details<br>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 (http://www.yellowcard.gov.uk) |
| **Records to be kept** | Complete record of consultation for smoking cessation + varenicline which includes;<br>• Patients name, date of birth, postcode and consent given<br>• Name and address of GP<br>• Varenicline assessment form<br>• Dose and form administered/supplied<br>• Batch and expiry date details<br>• Communications with GP |

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| | • Advice given to patient (including side effects)<br>• Signature of Pharmacist<br>• Signature of patient<br>• Any ADR<br>Input data onto PharmOutcomes |

**Patient information**

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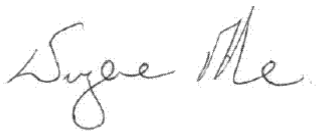
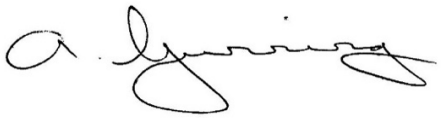
| **Information to be given to patient** | • Clients should be advised to set a quit date 7 to 14 days after initiation<br>• The major reasons for varenicline failure are:<br>- Unrealistic expectations<br>- Lack of preparation for the fact that the tablets may cause nausea<br>- Insufficient or incorrect use<br>• It is important to make sure that the client understands the following points:<br>1. Varenicline is not a magic cure - effort and determination are crucial<br>2. It works by acting on the parts of the brain which are affected by nicotine in cigarettes<br>3. It does not remove all temptation to smoke, but it does make abstinence easier<br>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<br>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<br>• 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<br>• Caution on the effects on driving and performance of skilled tasks – increased risk of dizziness, somnolence and transient loss of consciousness |
| 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). |

## Appendices

### *Appendix A. Key references*


1. Summary of Product Characteristics (SPC) for Champix. 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 Review Working Group(2019)*

| Name | Job title and organisation | Signature | Date |
|---|---|---|---|
| Lead doctor - Eugene Milne | Director of Public Health, Newcastle City Council |  | 03/09/19 |
| Lead pharmacist - Andre Yeung | Senior Specialist Advisor, Newcastle City Council |  | 03/09/19 |
| Representative of other professional group using PGD- Ann Gunning | Head of Services and Support North of Tyne LPC |  | 03/09/19 |
| **Other members of the PGD working group** | | | |
| Lynda Seery | Public Health Specialist/ Commissioner Newcastle City Council |  | 03/09/19 |
| David Fellows | Public Health and Wellbeing Officer, North Tyneside Council |  | 03/09/19 |

### *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.

| Name of Pharmacist | Signature | Registration Number | Authorising Manager | Date |
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