

**Patient Group Direction**  
**for the supply of**  
***VARENICLINE***  
**by Community Pharmacists**

**Version 8**

**Valid from: 1<sup>st</sup> September 2020**

**Expiry date: 31<sup>st</sup> August 2022 (or earlier if clinically necessary)**

Summary of changes from version 7

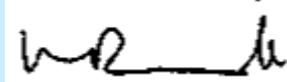
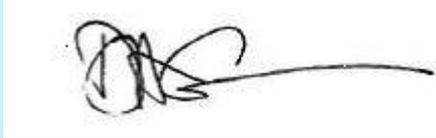
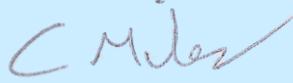
- Removed history of seizures from cautions as it is included in exclusions
- Exclusion and cautions for psychiatric illness updated
- Contact details for NHS services updated and minor updates to formatting.

**PGD development:**

|                    | Name and Job Title   | Date                   |
|--------------------|--|------------------------|
| <b>Written by</b>  | Tom Gregory<br>Medicines Optimisation Pharmacist<br>Bristol, North Somerset and South Gloucestershire<br>CCG                     | June 2018              |
| <b>Reviewed by</b> | Michelle Jones<br>Senior Medicines Optimisation Pharmacist (Bristol)<br>Bristol, North Somerset and South Gloucestershire<br>CCG | July 2018<br>July 2020 |

**PGD authorisation**North Somerset Council

This patient group direction has signed on behalf of North Somerset Council by:

|                                | Name and Job Title   | Signature  | Date                            |
|--------------------------------|--|--|---------------------------------|
| Doctor                         | Dr Peter Brindle<br>Medical Director (Clinical<br>Effectiveness)<br>NHS Bristol, North Somerset and<br>South Gloucestershire CCG |  | 17 <sup>th</sup> August<br>2020 |
| Pharmacist                     | Debbie Campbell<br>Deputy Director (Medicines<br>Optimisation)<br>NHS Bristol, North Somerset and<br>South Gloucestershire CCG   |  | 17 <sup>th</sup> August<br>2020 |
| Commissioner<br>Representative | Christopher Miles<br>Health Improvement Advanced<br>Specialist<br>North Somerset Council   |  |                                 |

## Patient group direction (PGD) for the supply of varenicline

This Patient Group Direction (PGD) is a specific written instruction for the supply of varenicline by accredited pharmacists to groups of patients within the area covered by North Somerset Council.

The majority of clinical care should be provided on an individual patient basis. The supply of medicines under Patient Group Directions should be reserved for those situations where this offers an advantage for patient care (without compromising patient safety) and where it is consistent with appropriate professional relationships and accountability. This PGD should be used in conjunction with the local smoking cessation service.

### Staff Characteristics

This PGD requires that a pharmacist has;

- Registered with the GPhC, met the conditions specified by the Commissioner and completed the Declaration of Competence process for this service to provide assurance of competence and confirm the requirements to provide the service have been met.
- Undertaken appropriate training to be a smoking cessation advisor, or is working with an appropriately trained smoking cessation advisor. The smoking cessation advisor may be either working within the pharmacy, or be a community advisor who has referred a client to a pharmacy for treatment with varenicline
- Undertaken appropriate training for working under patient group directions for the supply and administration of medicines
- Made themselves familiar with the information on varenicline in the current BNF and keeps up to date with any changes to recommendations for this medication.
- Agreed to be professionally accountable for their practice in accordance with the GPhC. In the exercise of professional accountability there is a requirement to maintain and improve their professional knowledge and competence
- Signed, and retained in-store, a copy of this document

### Incident Reporting

- All incidents need to be reported in accordance with the local incident reporting policy.

| Clinical Details   |   |
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| Indication         | For adults who are accessing Smokefree services and are in need of pharmacological treatment as an aid to stop smoking. Smokefree services may be either pharmacy- or community-based, though the supply of varenicline will be made from a registered pharmacy   |
| Inclusion criteria | <ul style="list-style-type: none"> <li>• Dependent smoker (i.e. they smoke within 30 minutes of waking up and/or find quitting unaided difficult)</li> <li>• Smoker aged over 18 who has approached the Smokefree service and who satisfies the criteria for treatment by the stop smoking service</li> <li>• The patient should set a date to stop smoking. Varenicline dosing should start 1-2 weeks before this date.</li> <li>• Patient should be motivated and willing to continue a course of treatment which includes behavioural support for 12 weeks unless unable to because of side effects</li> <li>• Valid consent</li> </ul>  |
| Exclusion criteria | <ul style="list-style-type: none"> <li>• Patient under 18 years of age;</li> <li>• Tobacco users not sufficiently motivated to quit or to use varenicline</li> <li>• Pregnancy</li> <li>• Breast-feeding</li> <li>• Patients with end-stage renal disease (defined as eGFR of less than 15mL/min) due to insufficient evidence in this group</li> <li>• Patients with <b>pre-existing or history of serious</b> psychiatric illness including schizophrenia, bipolar disorder or major depressive illness. Such patients should be referred to their GP.</li> <li>• Patients with unstable cardiovascular disease.</li> <li>• Clients with hypersensitivity to varenicline or any of its excipients</li> <li>• Patients with epilepsy, a history of seizures or conditions that lower the seizure threshold.</li> <li>• Patients currently being prescribed varenicline or using other pharmacotherapies for smoking cessation, i.e. bupropion and nicotine replacement therapies.</li> </ul> |

Cautions

- Varenicline should be used with caution in patients with an eGFR of 15-29mL min (see dose section for more information)
- Physiological changes resulting from smoking (with or without the use of varenicline) may result in changes to the pharmacokinetics of some drugs for which dose adjustment may be necessary (examples include warfarin, theophylline and insulin). Refer to current edition of the BNF.
- Varenicline should be used with caution in patients who are taking medicines which may lower the seizure threshold
- Patients with pre-existing or a history of cardiovascular disease should be advised to stop taking varenicline and seek advice from their GP if they feel their symptoms are worsening. Advise that medical help is sought right away if they have symptoms of a heart attack or stroke.

**Psychiatric illness**

- Caution is advised in patients with pre-existing or a history of mild or moderate psychiatric disorders including depression due to the risk of exacerbating any underlying condition.

Changes in behaviour have been reported in patients attempting to quit smoking in the post-marketing surveillance, however 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 side effects compared to placebo.

Smoking cessation with or without pharmacotherapy has been associated with the exacerbation of underlying psychiatric disorder.

Caution is also advised in patients newly starting on an antidepressant as they can be at increased risk of suicidal thoughts and behaviour.

Patients should be told to stop treatment and contact their doctor immediately if they develop suicidal thoughts or behaviour. See “advice to patient” for further information.

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| Management of excluded patients | <p>Explain the reasons for exclusion under the PGD to the client. Where appropriate ensure they are advised to attend their GP practice to discuss whether treatment by a prescriber is possible.</p> <p>Nicotine replacement therapy may be considered as an option for clients who still wish to stop smoking</p> <p>Document reasons for exclusion and record any actions taken.</p> |
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| Drug Details                      |  |
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| Name, form & strength of medicine | Varenicline (Champix®) 0.5mg and 1mg tablets   |
| Route/method                      | Varenicline tablets should be swallowed whole with water and can be taken with or without food   |
| Legal classification              | POM – Prescription only medicine.  |
| Dosage, duration and frequency    | <p>The recommended dose of varenicline is 1mg twice-daily following a 1 week titration period as follows:</p> <p><b>Days 1-3</b> : 0.5mg once daily<br/> <b>Days 4-7</b>: 0.5mg twice daily</p> <p><b>Day 8 onwards</b>: 1mg twice daily</p> <ul style="list-style-type: none"> <li>• The usual duration of treatment is 12 weeks, with the client aiming to stop smoking within the first 7-14 days, but this can be up to 5 weeks after starting varenicline</li> <li>• 14 day prescription packs should be used routinely throughout the quit attempt, though if treatment is likely to be interrupted, for example by holidays where the client is unable to attend for a supply, a <b>maximum</b> of 28 days be supplied at any one time.</li> <li>• Patients should be seen weekly for at least 4 weeks after the quit date.</li> <li>• Patients with moderate renal impairment (creatinine clearance 30 - 50mL/min) may require a dose reduction to 1mg once daily if intolerable side effects are experienced. The maximum dose for patients with severe renal impairment (eGFR 15-29mL/min) is 0.5mg daily for the first three</li> </ul> |

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|                    | <p>days, increasing to 1mg once daily.</p> <ul style="list-style-type: none"> <li>• Patients who cannot tolerate varenicline because of adverse effects e.g. nausea which is not ameliorated by taking with food, the dose can be lowered to 0.5mg twice daily. If used, this lower dose should be reviewed at the follow up appointment.</li> <li>• For patients who have successfully stopped smoking at the end of 12 weeks, one additional course of up to 12 weeks treatment with varenicline at 1 mg twice daily may be considered based on consultation with the client to reduce risk of relapse.</li> <li>• In patients with a high risk of relapse, dose tapering may be considered at the end of the course. The dose tapering would occur at the end of week 12 for an <b>additional</b> 2 weeks and would involve using a titration pack in reverse.</li> </ul> |
| Quantity to supply | <p><b>Titration:</b> 1x 25 tablet varenicline 0.5mg / 1mg titration pack</p> <p><b>Maintenance:</b> 1x 28 pack varenicline 1mg tablets<br/><i>(2x28 may be supplied in exceptional circumstances where treatment may be interrupted, for example due to holiday)</i></p>   |

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| Advice to patient | <p>Patients should be advised to set a quit date, usually 7 to 14 days after initiation;</p> <p>The major reasons for varenicline failure are:</p> <ul style="list-style-type: none"> <li>• Unrealistic expectations;</li> <li>• Lack of preparation for the fact that the tablets may cause nausea</li> <li>• Insufficient or incorrect use.</li> </ul> <p>It is important to make sure that the patient understands the following points:</p> <ol style="list-style-type: none"> <li>1. Varenicline is not a magic cure, it works in conjunction with behavioural support</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 ('it takes the edge off the discomfort');</li> <li>4. <b>Patients should be told to stop treatment and</b></li> </ol> |
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|  | <p><b>contact their doctor immediately if they develop suicidal thoughts or behaviour</b></p> <p>5. Patients should be advised to discontinue treatment with varenicline if agitation, depressed mood or changes in behaviour or thinking that are of concern to the patient, pharmacist, doctor, family or care-givers are observed.</p> <p><b>6. Patients with pre-existing cardiovascular disease should be advised to stop taking varenicline and seek advice from their GP if they feel their symptoms are worsening. Advise that medical help is sought right away if they have symptoms of a heart attack or stroke.</b></p> <p>7. Instruct on correct use and daily dose. Use the manufacturer's product packaging for the explanation. Patients should take varenicline for 7 to 14 days before stopping smoking.</p> <p>8. About a third of patients may experience mild nausea some 30 minutes after taking it. This reaction usually diminishes gradually over the first few weeks, and most patients tolerate it without problems, and may be improved by taking varenicline with food</p> <p>9. Varenicline may cause dizziness and somnolence and therefore may influence the ability to drive and use machines. Patients are advised not to drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether this medicinal product affects their ability to perform these activities.</p> <p><b>10. Upon stopping treatment with varenicline, patients may experience an increase in irritability, urge to smoke, depression and/or insomnia. This can occur in up to 3% of patients.</b></p> <p>11. In clinical trials and from post-marketing experience there have been reports of seizures in patients with or without a history of seizures, treated with varenicline. Having a seizure affects your legal ability to drive; it is a legal requirement to notify the DVLA</p> |
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| Side effects | <p>Pharmacists can refer to the SPC for varenicline for more detailed information.<br/> <a href="http://www.medicines.org.uk/emc/default.aspx">www.medicines.org.uk/emc/default.aspx</a></p> <p>Adverse effects include, but are not limited to:</p> |
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|   | <p><b>Very Common</b></p> <ul style="list-style-type: none"> <li>• Abnormal dreams</li> <li>• Insomnia</li> <li>• Headache</li> <li>• Nausea</li> </ul> <p><b>Common</b></p> <ul style="list-style-type: none"> <li>• Somnolence</li> <li>• Dizziness</li> <li>• Dysgeusia (taste disturbance)</li> <li>• Vomiting</li> <li>• Constipation</li> <li>• Diarrhoea</li> <li>• Abdominal distension</li> <li>• Stomach discomfort</li> <li>• Dyspepsia</li> <li>• Flatulence</li> <li>• Dry mouth</li> <li>• Fatigue</li> </ul> <p>Patients should be aware that smoking cessation and nicotine withdrawal are also associated with symptoms such as increased appetite, weight gain, insomnia and irritability.</p> <p>Seizures are an uncommon side-effect. Patients who are concurrently taking a medicine which lowers the seizure threshold should be made aware of the possibility of a drug interaction which may result in a seizure, though there is no evidence to support an increased risk compared to that of varenicline alone. Seizures have been reported in patients with and without a history of seizures while taking varenicline and varenicline should be used with caution.</p> <p>Pharmacists operating under this PGD should be aware of the possibility of neuropsychiatric side effects. If any such side effects occur, patients should be advised to stop varenicline immediately and to contact a healthcare professional for advice.</p> |
| Reporting procedure for adverse reactions | <p>Varenicline is no longer a “black triangle” drug, however any <b>serious</b> adverse events should still be reported using the ‘Yellow Card’ reporting system (<a href="https://yellowcard.mhra.gov.uk/">https://yellowcard.mhra.gov.uk/</a>)</p>  |

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| Supplies and resources that must be available at sites where this PGD is in use | <ul style="list-style-type: none"> <li>• A copy of this PGD</li> <li>• Access to latest Summary of Product Characteristics for varenicline (available at <a href="http://www.medicines.org.uk">www.medicines.org.uk</a>)</li> <li>• Latest version of the British National Formulary</li> <li>• Information about services involved in providing healthy lifestyles</li> <li>• It is the responsibility of the individual pharmacist to ensure that they and their staff are competent in all aspects of the supply of varenicline and are updated on current medicines policies.</li> </ul>  |
| Ongoing supplies of varenicline   | Pharmacists must satisfy themselves on that the patient is still eligible to receive treatment with varenicline <b>at each supply</b> . This should include a re-examination of the exclusion criteria such as recent onset of depressive symptoms and any seizure disorders.   |
| Records and audit trail   | <p>Record the supply in the patient's medication record and the information required into the PharmOutcomes template for varenicline supply which will include:</p> <ul style="list-style-type: none"> <li>• Patient's name, address, date of birth and GP details</li> <li>• Date supplied &amp; Name of the pharmacist who supplied the medication</li> <li>• Start date and Quit date</li> <li>• Batch number and expiry date</li> <li>• Quantity supplied and dose advised</li> <li>• Reason for inclusion;</li> <li>• Advice given to patient;</li> <li>• Pharmacists <b>must</b> ensure that documentation is sent to the patients GP informing them that varenicline has been issued under a PGD</li> <li>• Details of any adverse drug reaction and actions taken including documentation in the patient's medical record via GP</li> </ul> |
| Follow up   | Clients should be seen weekly by the smoking cessation advisor for the first four weeks to assess compliance and provide behavioural support, and be seen by the supplying pharmacist routinely every two weeks to ensure ongoing suitability to receive varenicline. This may in exceptional circumstances be extended to four weeks as discussed above.   |

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| Reference to national/local policies or guidelines | <ul style="list-style-type: none"><li>• NICE Technology Appraisal – Smoking Cessation: Varenicline, July 2007)</li><li>• Summary of Product Characteristics, Champix®</li><li>• Neuropsychiatric safety and efficacy of varenicline, bupropion, and nicotine patch in smokers with and without psychiatric disorders (EAGLES): a double-blind, randomised, placebo-controlled clinical trial, <i>The Lancet</i>, (2016), volume 387 p2507-2520</li></ul> <p><u>Clients wanting more information can be referred to:</u></p> <ul style="list-style-type: none"><li>• Smokefree North Somerset: 01275 546 774</li><li>• The NHS Smokefree Helpline: 0300 123 1044;</li></ul> |
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