Patient Group Direction

for the supply of

VARENICLINE
by Community Pharmacists

Version Six

Valid from: 1st September 2016

Expiry date: 31st August 2018 (or earlier if clinically necessary)

PGD Reference Number: NS/65/16

An electronic copy of this PGD can be accessed from the Avon LPC website

Changes in version 6:

- Age restriction 18-75 (as per EAGLES trial)
- Inclusions and exclusions updated – previous depression no longer excluded
- Medicines lowering seizure threshold no longer an exclusion in absence of a seizure disorder
- Dose tapering at end of course as per SPC
- Warning about risk of seizure and neuropsychiatric side effects
- No longer black triangle

	Name and Job Title
Updated by	Tom Gregory Medicines Optimisation Pharmacist, North Somerset CCG
Reviewed by	Dan Stephens Medicines Optimisation Pharmacist, North Somerset CCG

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

	Name and Job Title	Signature	Date
Doctor	Dr Mary Backhouse Chief Clinical Officer NHS North Somerset CCG		31/8/16
Pharmacist	Debbie Campbell Head of Medicines Management NHS North Somerset CCG		30/8/2016
Public Health Representative	Natalie Field Director of Public Health North Somerset Council		15.9.2016

This patient group direction has been approved on behalf of South Gloucestershire Council by:

	Name and Job Title	Signature	Date
Doctor	Dr Mark Pietroni Director of Public Health		
Pharmacist	Mel Green Director of Medicines Management		
Public Health Representative	Jacqui Offer Specialist Public Health Manager		

Patient Group Direction (PGD) for the supply of VARENICLINE

This Patient Group Direction (PGD) is a specific written instruction for the supply of **VARENICLINE** to groups of patients within the area covered by North Somerset Council and South Gloucestershire Council.

This PGD will enable designated **COMMUNITY PHARMACISTS** to supply treatment in accordance with the following protocol and the recommendations of the Department of Health.

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.

Background information

This PGD is a written with the objective of allowing the supply of a Prescription Only Medicine (POM) on the NHS by health professionals who do not have prescribing rights.

Varenicline (Champix ^{TM} in the UK) was launched as a POM for smoking cessation in December 2006. It was approved for use in Scotland by the Scottish Medicines Consortium in January 2007; and for use in England and Wales by the National Institute of Health and Clinical Excellence (NICE) in July 2007. The main recommendations of both documents are consistent:

- Varenicline is recommended within its licensed indications as an option for smokers who have expressed a desire to quit smoking.
- Varenicline should normally be prescribed only as part of a programme of behavioural support.

The purpose of this PGD is to enable a pharmacist working in North Somerset and/or South Gloucestershire, who has received training and has been assessed as competent, and is trained as, or is working with a smokefree advisor to supply varenicline in accordance with this PGD.

The MHRA has advised that medicines supplied under a PGD would usually be considered to be "dispensed medicines". It is therefore considered appropriate for such medicines to be supplied to patients with the same labelling and other information which they would otherwise receive if the medicine had been supplied against a prescription. In a majority of cases, the pack to be issued under a PGD will need to be labelled to reflect the dose exactly as authorised in the PGD, as if it were being dispensed against a prescription.

1. Clinical condition or situation to which the direction applies

Indication	For adults who are accessing Pharmacy Stop Smoking Services and are in need of pharmacological treatment as an aid to stop smoking
Criteria for inclusion	• Dependent smoker (i.e. they smoke within 30 minutes of waking up and/or find quitting unaided difficult) • Smoker aged between 18 and 75 who has approached the Stop Smoking Service and who satisfies the criteria for treatment by the stop smoking service and as per the North Somerset Protocol • The patient should set a date to stop smoking. Varenicline dosing should start 1-2 weeks before this date. • Patient should be willing to continue a course of treatment which includes behavioural support for 12 weeks unless unable to

	because of side effects • Valid consent
Criteria for exclusion	• Patient under 18 years of age; • Patient over 75 years of age • Tobacco users not sufficiently motivated to quit • Pregnancy • Breast-feeding • Patients with end-stage renal disease (defined as eGFR of less than 15mL/min) due to insufficient evidence in this group • Varenicline should be used with caution in patients with an eGFR of 15-29mL min (see dose for more information) • Patients with a current psychiatric illness including depression. Such patients should be referred to their GP. • Patients with a history of any psychiatric illness, excluding depression (patients with a previous history of depression are not excluded, defined as patients no longer being treated for depression) • Patients with unstable cardiovascular disease. • Clients with hypersensitivity to varenicline or any of its excipients • Patients with Epilepsy, a history of seizures or conditions that lower the seizure threshold.
Action if excluded	Explain the reasons for exclusion under the PGD to the patient. Where appropriate ensure they are advised to attend their GP practice to discuss whether treatment by the GP is possible.
2. Description of treatment	
Name of Drug & Strength	Varenicline (Champix) 0.5mg and 1mg
Formulation	Film coated Oral Tablets
Method/route	Varenicline tablets should be swallowed whole with water and can be taken with or without food
Dose, dose range, frequency of administration and quantity to supply	Patients should be treated for 12 weeks. There should be clear labelling to indicate instructions to follow for the course. <u>Days 1 – 3</u>: 0.5 mg (white tablets) once daily <u>Days 4 – 7</u>: 0.5 mg twice daily <u>Day 8 to the end of treatment</u>: 1 mg (light blue tablets) twice daily Patients should be supplied a 14 day initiation pack and should set a quit date, which is usually 7 to 14 days after initiation, but can be between 1 – 5 weeks after starting varenicline 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 maximum of 28 days be supplied at any one time. Patients should be seen weekly for at least 4 weeks after the quit date Patients with moderate renal impairment (creatinine clearance between 30 to 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 days, increasing to 1mg once daily. As noted in the exclusion criteria above, varenicline is contraindicated in patients with an eGFR of less than 15mL/min. 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. 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 and as per the NHS North Somerset protocol. **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 additional 2 weeks and would involve using a titration pack in reverse.**
Legal status	POM – Prescription only medicine.
Advice to be given to the patient before treatment is provided	• Patients should be advised to set a quit date, usually 7 to 14 days after initiation; • The major reasons for varenicline failure are: o Unrealistic expectations; o Lack of preparation for the fact that the tablets may cause nausea o Insufficient or incorrect use. • It is important to make sure that the patient understands the following points: 1. Varenicline is not a magic cure, it works in conjunction with behavioural support 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, but it does make abstinence easier (‘it takes the edge off the discomfort’); **4. Patients should be told to stop treatment and contact their doctor immediately if they develop suicidal thoughts or behaviour**

	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. **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.** 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. 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 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. **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.** 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
Identification and management of adverse reactions	Pharmacists can refer to the SPC for varenicline for more detailed information. www.medicines.org.uk/emc/default.aspx The very common (> 1 in 10; and common effects > 1 in 100) are: Very Common • Abnormal dreams • Insomnia • Headache • Nausea Common • Somnolence • Dizziness • Dysgeusia (taste disturbance) • Vomiting • Constipation • Diarrhoea • Abdominal distension • Stomach discomfort • Dyspepsia • Flatulence,

	• Dry mouth • Fatigue Patients should be aware that smoking cessation and nicotine withdrawal are also associated with symptoms such as increased appetite, weight gain, insomnia and irritability. **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 sezures while taking varenicline and varenicline should be used with caution.** **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.**
Reporting procedure for adverse reactions	Varenicline is no longer a "black triangle" drug, however any adverse effects should still be reported using the 'Yellow Card' reporting system (https://yellowcard.mhra.gov.uk/)
Supplies and resources that must be available at sites where this PGD is in use	• A copy of this PGD • Access to latest Summary of Product Characteristics for varenicline (available at www.medicines.org.uk) • Latest version of the British National Formulary • Information about services involved in providing healthy lifestyles 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.
Ongoing supplies of varenicline	Pharmacists must satisfy themselves on that the patient is still eligible to receive treatment with varenicline **at each supply.** This should include a re-examination of the exclusion criteria such as recent onset of depressive symptoms and any seizure disorders.
Additional Facilities	Consulting Room
Records to be kept for legal and audit purposes	**Documentation is available from the Avon LPC website** • Patient's name, address, date of birth and GP details • Date supplied & Name of the pharmacist who supplied the medication • Start date and Quit date • Batch number and expiry date

	• Quantity supplied and dose advised • Reason for inclusion; • Advice given to patient; • Pharmacists **must** ensure that documentation is sent to the patients GP informing them that varenicline has been issued under a PGD • Details of any adverse drug reaction and actions taken including documentation in the patient's medical record via GP • Varenicline is no longer "black triangle", however adverse reactions should still be reported via the MHRA Yellow Card scheme.
3. Characteristics of staff It is the professional responsibility of the Health Care professional to work within their level of competence. The healthcare professional will ensure he/she has the relevant training and is competent to work under this PGD.	
Qualification requirements	Pharmacist (registered with the GPhC and either trained themselves or working with a smokefree advisor. The local Smokefree Service will provide pharmacists with training on local protocols. This training is mandatory before supply under this PGD can commence.
Reference to national/local policies or guidelines	• NICE Technology Appraisal – Smoking Cessation: Varenicline, July 2007) • Summary of Product Characteristics, Champix® • North Somerset CCG PGD Policy, version 2 • 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, *The Lancet*, (2016), volume 387 p2507-2520 Clients wanting more information can be referred to: Smokefree North Somerset: 01275 546774 Smokefree South Gloucestershire: 01454 865502 The NHS Smoking Helpline: 0800 169 0 169; Quit line:0800 002200

Individual Pharmacist Authorisation – North Somerset and South Gloucestershire Patient Group Direction for the supply of varenicline by Community Pharmacists.

If a declaration of competence has been made via PharmOutcomes, it is not necessary to complete this page.
A Pharmacist must sign this page for each pharmacy in which they are supplying varenicline using this PGD

I have read and understood the Patient Group Direction (PGD) and agree to supply this medicine only in accordance with this PGD.
PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY. It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own code of professional conduct.

Name of Pharmacy			
Address of Pharmacy			
Pharmacist name (Print)			
Pharmacist signature			
Date form signed			
Date of last training attended			

Return either via post to:

Smokefree North Somerset Admin, Town Hall, Walliscote Grove Road, Weston-super-Mare, BS23 1UJ (NS)

Smokefree South Gloucestershire, Department for Children, Adults & Health, PO Box 298, Health & Wellbeing Division (Stop Smoking Service), Civic Centre, High Street, Kingswood, Bristol BS15 0DQ.

Or scan and email:

smokefree@n-somerset.gov.uk
smokefree@southglos.gov.uk