Patient Group Direction

Supply of Varenicline (Champix ®) By authorised Community Pharmacists working in NHS Forth Valley Protocol number 445 Version 5

Date protocol prepared: **March 2021**

Date protocol due for review: **March 2023**

Expiry Date: **March 2024**

This patient group direction must be signed by all health care professionals involved in its use. The NHS organisation should hold the original signed copy. The PGD must be easily accessible in the clinical setting.

Organisation	NHS Forth Valley

Job Title	**Name**	**Signature**	**Date**
Director of Nursing	Angela Wallace	Signed by Angela Wallace	16/4/21
Medical Director	Andrew Murray	Signed by Andrew Murray	6/4/21
Director of Pharmacy	Scott Mitchell	Signed by Scott Mitchell	19/4/21

This document authorises the supply of **Varenicline** by appropriate practitioners to patients who meet the criteria for inclusion under the terms of the document.

Practitioners seeking to supply **Varenicline** must ensure that they assess all clients to make sure they meet the criteria before supplying the product.

The purpose of this Patient Group Direction is to help patients by ensuring that they have ready access to a quality assured service which provides a timely, consistent and appropriate supply of **Varenicline** for the treatment of patients.

Signatures of those developing the Patient Group Direction

Job Title	Name	Signature	Date
Doctor	David Herron	Signed by David Herron	1/4/21
Pharmacist	Kirstin Cassells	Signed by Kirstin Cassells	1/4/21
Nurse			
Microbiologist (if appropriate)			
Paediatrician (if appropriate)			

Approval from Patient Group Directions Group

	Chair	Signed on behalf of group	Date
Patient Group Directions Group	Scott Mitchell	Signed by Scott Mitchell	**19/4/21**

Lead Author responsible for updating change history: Kirstin Cassells

Change history

Version	Date	Summary of changes
5	26/1/21	Caution/ Need for further advice section updated to include headings. Section added to include information on history of cardiovascular disease.
5	26/1/21	Minimum/Maximum section updated to 12 weeks.
5	26/1/21	Advice to patient/carer section updated to include the following points: Varenicline does not guarantee abstinence from smoking, effort and determinations are crucial. Varenicline works by acting on the parts of the brain which are affected by nicotine in cigarettes. Varenicline does not remove all the temptation to smoke, but it does make abstinence easier (it takes the edge off the discomfort by reducing the severity of tobacco withdrawal symptoms such as craving to smoke, irritability, poor concentration and low mood). It can also take away the enjoyment from smoking. About a third of individuals may experience mild nausea usually about 30 minutes after taking it. This reaction often diminishes gradually over the first few weeks and most individuals tolerate it without problems.
5	26/1/21	Specialist competencies and qualifications section updated to reflect move to TURAS Learn module.
5	26/1/21	Reference sources and comments section updated to reflect date SPC was accessed and website link added to NICE reference.

The following Patient Group Direction for Supply of Varenicline by authorised Community Pharmacists working in NHS Forth Valley may be used from the following business/practice:

Name:

Address:

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

CLINICAL CONDITION

Indication	Clients accessing the pharmacy smoking cessation service who wish to stop smoking.
Inclusion Criteria	• Dependent smoker (i.e. they smoke within 30 minutes of waking up and /or find quitting unaided difficult) identified as sufficiently motivated to quit • Clients aged 18 years of age and over • The client agrees to receive ***behavioural support*** according to the agreed protocol
Exclusion Criteria	• Smokers not sufficiently motivated to quit • Client under 18 years of age • Pregnant or breastfeeding women • Sensitivity to varenicline or any of its excipients • End stage renal disease e.g. on dialysis. • Not to be used in conjunction with other smoking cessation therapies
Caution/ Need for further advice	**Renal Impairment** For patients with moderate renal impairment who experience adverse reactions that are not tolerable, dosing may be reduced to 1 mg once daily. For patients with severe renal impairment (estimated creatinine clearance < 30 ml/min), the recommended dose of varenicline is 1 mg once daily. Dosing should begin at 0.5 mg once daily for the first 3 days then increased to 1 mg once daily. **Seizures** In clinical trials and post-marketing experience there have been reports of seizures in patients with or without a history of seizures, treated with varenicline. Varenicline should be used cautiously in patients with a history of seizures or other conditions that potentially lower the seizure threshold. Discuss with GP or offer NRT as alternative.

	Psychiatric Disorders The use of varenicline in patients with or without a history of psychiatric disorder was not associated with an increased risk of serious neuropsychiatric adverse events in the composite primary endpoint compared with placebo. **History of Cardiovascular Disease** Individuals taking varenicline should be instructed to notify their doctor of new or worsening cardiovascular symptoms and to seek immediate medical attention if they experience signs and symptoms of myocardial infarction or stroke. Interactions with Other Medical Products Physiological changes resulting from smoking cessation, with or without treatment with varenicline, may alter the pharmacokinetics or pharmacodynamics of some medicinal products, for which dosage adjustment may be necessary (examples include theophylline, warfarin, clozapine and insulin). Clients taking medications that may be affected when they stop smoking should be advised to tell their treating physician of their quit attempt.
Action if Patient declines or is excluded	If patient declines Discuss alternative products if suitable and/or offer a referral to the Specialist Smoking Cessation service for further assessment. If patient excluded Refer Specialist Smoking Cessation Service or GP Practice. Patients who are excluded from the use of varenicline may be suitable for smoking cessation support using NRT.

DRUG DETAILS

Name, form & strength of medicine	Varenicline (Champix®) Tablets 500 mcg and 1mg film coated tablets
Legal Status	POM
Route/ Method	Oral
Dosage	**Days 1 - 3:** 500 mcg (white tablets) once daily **Days 4 – 7:** 500 mcg tablets twice daily **Day 8 to the end of the treatment:** 1mg (blue tablets) twice daily for 11 weeks. (Reduce to 500 mcg twice daily if not tolerated) Maximum single dose 1mg Maximum daily dose 2mg

	Client should set a date to stop smoking. Client should start taking varenicline 1-2 weeks before this date. Tablets should be swallowed whole with plenty of water and can be taken with or without food. Patients who cannot tolerate the adverse effects of varenicline may have the dose lowered temporarily or permanently to 500 mcg twice daily. **For patients with known severe renal impairment (estimated creatinine clearance < 30 ml/min)** The maximum dose of varenicline is 1 mg once daily. Dosing should begin at 500 mcg once daily for the first 3 days then increased to 1 mg once daily.
Frequency	As detailed under dosage
Duration of treatment	12 weeks
Maximum or minimum treatment period	12 weeks
Quantity to Supply/ administer	See dosage
Side Effects	• Nausea • Sleep disorders/ abnormal dreams • Headache • Appetite changes • Dry mouth /taste disturbances • Drowsiness • Dizziness For a full list of side effects – refer to the marketing authorisation holder's Summary of Product Characteristics (SPC). A copy of the SPC must be available to the health professional administering medication under this Patient Group Direction. This can be accessed on www.medicines.org.uk All adverse reactions that are serious or result in harm should be reported to the MHRA through the Yellow Card Scheme https://yellowcard.mhra.gov.uk/ . No clinical meaningful drug interactions have been reported. When varenicline and transdermal NRT are co-administered to smokers, this results in an increased incidence of known side effects
Advice to patient/carer	**It is important to make sure the client understands the following points:** • Varenicline does not guarantee abstinence from smoking, effort and determination are crucial

	• Varenicline works by acting on the parts of the brain which are affected by nicotine in cigarettes • Varenicline does not remove all the temptation to smoke, but it does make abstinence easier (it takes the edge of fthe discomfort by reducing the severity of tobacco withdrawal symptoms such as craving to smoke, irritability, poor concentration and low mood). It can also take away the enjoyment from smoking. • About a third of individuals may experience mild nausea usually about 30 minutes after taking it. This reaction often diminishes gradually over the first few weeks and most individuals tolerate it without problems. • Advice to clients should include specific product advice on dosage, method of administration and side effects. See Appendix 1 for treatment plan • Provide clients with the patient information leaflet from the packaging • If client experiences any significant side effects they should seek medical advice **The following general advice should also be given**: • Follow-up and obtaining further supplies • Possible changes in the body on stopping smoking e.g. weight gain • At the end of treatment, discontinuation of varenicline has been associated with an increase in irritability, urge to smoke, and/or insomnia in up to 3% of patients. The pharmacist should inform the patient accordingly. Clients must be informed that information relating to the supply of varenicline under a PGD needs to be passed to other health service organisations in particular their GP and NHS Scotland to ensure proper record keeping and patient safety.
Follow up	

STAFF CHARACTERISTICS

Qualifications	Pharmacist currently on the practising section of pharmaceutical register held by the General Pharmaceutical Council.
Specialist competencies or Qualifications	Pharmacists must have the necessary competencies and training to use the PGD and be authorised to use the PGD by their Lead Pharmacist. To have satisfactorily completed the approved training: NES Scottish Pharmacy Smoking Cessation Programme and/or the equivalent TURAS Learn modules

	Under PGD legislation there can be no delegation. Supply of Varenicline has to be by the same practitioner who has assessed the patient under the PGD.
Continuing Training & Education	Pharmacists must have up to date knowledge of Varenicline evidenced through ongoing CPD.

REFERRAL ARRANGEMENTS & AUDIT TRAIL

Referral arrangements	
Records/audit trail	A record of supply should be made on PMR which includes: • Patient's name, address, date of birth and GP details; • Date supplied and name of the pharmacist who supplied the medication; • Reason for inclusion; • Advice given to patient; • Details of any adverse drug reaction and actions taken; • Advise GP that patient has commenced treatment with varenicline (see appendix 2 for example letter); All adverse reactions that are serious or result in harm should be reported to the MHRA through the Yellow Card Scheme https://yellowcard.mhra.gov.uk/ The medicine must be labelled in accordance with requirements detailed in the current version of Medicines, Ethics and Practice. The patient's GP must be notified that a supply has taken place. The patient's GP must be informed if the patient experiences an adverse drug reaction. A computer or manual record of all individuals receiving a supply under this PGD should also be kept for audit purposes. Record "supplied via Patient Group Direction (PGD)" Any adverse events/incidents should be reported to the PGD group in addition to any existing pharmacy processes Records of supply should be kept for 8 years.
Reference sources and comments	• British National Formulary (BNF) • Summary of Product Characteristics (SPC) for Champix®. https://www.medicines.org.uk/emc/medicine/19045 Accessed January 2021 • National Institute for Health and Clinical Excellence.

	Varenicline for smoking cessation. NICE technology appraisal 123, July 2007. https://www.nice.org.uk/guidance/TA123 • Medicines and Health Product regulatory Agency (MHRA) safety alert: October 2009 https://www.gov.uk/drug-safety-update/varenicline-and-suicidal-behaviour-cohort-study-provides-some-reassurance

PATIENT GROUP DIRECTION AUTHORISATION DOCUMENT

Supply of Varenicline (Champix®) by authorised Community Pharmacists working in Forth Valley Community Pharmacies protocol number 445 version 5

Individual Authorisation

This PGD does not remove inherent professional obligations or accountability

I_____ (please print in capitals), confirm that I have read and understood the above Patient Group Direction. I confirm that I have the necessary professional registration, competence, and knowledge to apply the Patient Group Direction. I will ensure my competence is updated as necessary. I will have ready access to a copy of the Patient Group Direction in the clinical setting in which the supply of the medicine will take place and agree to provide this medicine only in accordance with this PGD.

I understand that it is the responsibility of the pharmacist to act in accordance with the Code of Ethics for Pharmacists and to keep an up to date record of training and competency. I understand it is also my responsibility to ensure that all consultations with patients occur within a private and confidential area of the pharmacy.

I have read and fully understand the Patient Group Direction for the supply of Varenicline and agree to provide this medicine only in accordance with this PGD in NHS Forth Valley Community Pharmacies.

Name of Pharmacist (in block capitals)_____

GPhC Number _____ Employee ☐ Locum ☐ Relief Pharmacist ☐

If you are a locum please provide a contact email address: _____

Normal NHS Forth Valley Pharmacy Location
(Please state contractor code)

_____

Signature _____

Date _____

Note :
A copy of this agreement must be signed by each pharmacy practitioner who wishes to be authorised to use the PGD for Supply of Varenicline by Community Pharmacists working in Forth Valley Pharmacies.

Please return this page either by mail to Community Pharmacy Development Team, NHS Forth Valley Royal Hospital, Stirling Road, Larbert, FK5 4WR **OR** by email to fv.communitypharmacysupport@nhs.scot attaching a scanned / photographed image. A copy should be retained in each pharmacy premises you provide the service in.

PATIENT GROUP DIRECTION AUTHORISATION DOCUMENT

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Name of Premises & Contractor Code_____

Address of Premises_____

PROFESSIONAL AGREEMENT

I have read and confirm that I have understood the above named patient group direction. **The people below have been authorised to use this protocol.** I confirm that it is my professional responsibility to ensure all those signed below have had their professional registration confirmed as per normal company processes and have signed the necessary PGD paperwork* to enable them to work within the confines of this PGD.
*The professional signing the PGD paperwork accepts personal responsibility for having undertaken all the mandatory training requirements for the PGD.

Signature of **Lead Pharmacist** for the contractor code

Name (in block capitals)	Signature	Date

Name of Professional (IN BLOCK CAPITALS)	Registration Number	Signature	Date

Appendix 1

Treatment Plan

Consultations	Treatment plan
1st week- Assessment week	Client should set a quit date between the next 8-14 days. Supply 14 day starter pack (11 x 500 mcg tabs with 14 X 1mg tablets) *Make arrangement to see client again before tablets run out i.e. between days 10- 14
3rd week	Client should have set a quit date. Monitor carbon monoxide level. If client is still smoking, he/she should be informed that treatment with varenicline would have to be stopped if he/she continued to smoke. Supply 1mg varenicline tablets if required Make arrangement to see client the following week.
4th- 12th week	Monitor carbon monoxide level and check if client has stopped smoking. **If client is still smoking, treatment with varenicline should be stopped.** If client has quit smoking supply 1mg varenicline tablets as required. If side effects are tolerable then continue supplying Varenicline 1mg tablets as required. If client is troubled by side effects assess whether they are tolerable or whether supply should be stopped. Here you may discuss the option to dose taper at week 10 with aim of stopping varenicline after 12 weeks of treatment. Note: A 14 day starter pack (11 x 500mcg tabs with 14 x 1mg tabs) can be supplied for the last two weeks of treatment. Ensure the patient has clear instructions to take the tablets in the starter pack in reverse order to facilitate tapered discontinuation.

Appendix 2

GP Notification
Patient Treatment with Varenicline

EXAMPLE

Dear Dr

Patient's name:

Address:

DOB:

I saw the above patient at the pharmacy today and I have recommended and supplied him/her with **varenicline** tablets to help him/her give up smoking. The patient would be taking varenicline for a maximum of 12 weeks. Could you please add this medicine to the patient's medication records? No further action would be required from you, as the patient would be receiving all supplies of varenicline from my pharmacy. Please do not hesitate to contact me should you require further information.

Yours sincerely

(Signature)

(PRINT NAME)