Patient Group Direction for the supply of Varenicline to named patients registered on the Public Health Services (PHS) - Smoking Cessation Service attending community pharmacies in NHS Borders.

This document authorises the supply of Varenicline by Accredited Pharmacists to named patients registered on the Public Health Services (PHS) - Smoking Cessation Service attending community pharmacies in NHS Borders who meet the criteria for inclusion under the terms of the document

The Accredited Pharmacists seeking to supply Varenicline must ensure that all patients have been screened and meet the criteria before supply takes place

The purpose of this Patient Group Direction is to allow management of Smoking Cessation in NHS Borders by Accredited Pharmacists.

This direction was first authorised on: November 2016

The direction was reviewed and updated on: February 2019

The direction will be reviewed on: February 2020

Author of PGD: Adrian MacKenzie, Lead Pharmacist, Primary and Community Care.

Clinician Responsible for Training and Review: Catriona Davies, Health Improvement Specialist - Smoking Awareness Service Co-ordinator

Specialist clinical review by: Catriona Davies, Health Improvement Specialist - Smoking Awareness Service Co-ordinator

Patient Group Direction for the supply and/or administration of varenicline without a prescription for a named individual by Accredited Pharmacists contracted by NHS Borders to provide the Public Health Services (PHS) - Smoking Cessation Service .

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 over 18 years of age □ 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
Referral criteria and Precautions	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. 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.

Specials warnings	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). A large randomised, double-blind, active and placebo-controlled study was conducted to compare the risk of serious neuropsychiatric events in patients with and without a history of psychiatric disorder treated for smoking cessation with varenicline, bupropion, nicotine replacement therapy patch (NRT) or placebo. The primary safety endpoint was a composite of neuropsychiatric adverse events that have been reported in post-marketing experience. 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. 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	Discuss alternative products if suitable and/or offer a referral to the Specialist Smoking Cessation service for further assessment.	
Action if Included	Supply varenicline (Champix®) 500 mcg and 1mg tablets.	
Action if excluded	Refer to GP or Specialist Smoking Cessation Service. Patients who are excluded from the use of varenicline may be suitable for smoking cessation support using NRT.	
Details of treatment course	Drug name	Varenicline (Champix®) Tablets
	Strength and form	500 mcg and 1mg film coated tablets
	Route	Oral
	Legal status	**PoM** Prescription-only Medicine

	Dose(s)	**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 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.
Drug Interactions	No clinical meaningful drug interactions have been reported. When varenicline and transdermal NRT were co-administered to smokers for 12 days, there was a statistically significant decrease in average systolic blood pressure (mean 2.6 mmHg) measured on the final day of the study. In this study, the incidence of nausea, headache, vomiting, dizziness, dyspepsia, and fatigue was greater for the combination than for NRT alone.	
Side Effects	• Nausea • Sleep disorders/ abnormal dreams • Headache • Appetite changes • Dry mouth /taste disturbances • Drowsiness • Dizziness Please refer to BNF and SPC for full list.	

Advice and Support	Advice to clients should include specific product advice on dosage, method of administration and side effects. See Appendix 2 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.

Records - 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.

1. **The following records should be kept (either paper or computer based)**
   The GP practice
   The patient name and CHI number
   The medicine name, dose, route, time of dose(s), and where appropriate, start date, number of doses and or period of time, for which the medicine is to be supplied or administered
   The signature and printed name of the approved healthcare professional who supplied or administered the medicine
   Whether patient met the inclusion criteria and whether the exclusion criteria were assessed
   Quantity supplied / received and current stock balance
   Advise GP that patient has commenced treatment with varenicline (see appendix 3 for example letter)
   Severe adverse reactions should be reported to the MHRA using the 'Yellow Card' reporting system

2. **Preparation, audit trail, data collection and reconciliation**-
   Stock balances should be reconcilable with Receipts, Administration, Records and Disposals on a patient by patient basis.

3. **Storage**- Store between 2-8ºC

4. **Professional Responsibility -**
   - All Health Professionals will ensure he/she has the relevant training and is competent in all aspects of medication, including contra-indications and the recognition and treatment of adverse effects. He/she will attend training updates as appropriate.
   - Pharmacist must be registered with the GPhC and contracted to provide the Minor Ailment Service.
   - Sources of Evidence used for the PGD creation should be stated

5. **References**

- British National Formulary (BNF) current edition https://www.medicinescomplete.com/mc/
- Summary of Product Characteristics (SPC) for Champix®. Accessed February 2017 https://www.medicines.org.uk/emc/medicine/19045
- National Institute for Health and Clinical Excellence. Varenicline for smoking cessation. NICE technology appraisal 123, July 2007.
- Medicines and Health Product regulatory Agency (MHRA) safety alert: November 2008
- https://www.gov.uk/drug-safety-update/varenicline-and-suicidal-behaviour - cohort-study-provides-some-reassurance

Patient Group Direction for the supply and/or administration of Varenicline by health professionals employed by NHS Borders/GP Practice

This Patient Group Direction is approved for use by the under-signed :			
Job Title	**Name**	**Signed**	**Date**
Senior Doctor/Dentist for relevant clinical area	Dr Cliff Sharp		20/2/19.
NHS Borders Director of Pharmacy	Alison Wilson		7/2/19
NHS Borders Senior Health Professional for Clinical Area	Nicky Berry		20/2/19
PGD AUTHORISED ON 20/02/2019 **Signed by ADTC CHAIRPERSON:** ..... **Name:** ALISON WILSON			

The Health Professionals named below, being employees of NHS Borders are authorised to supply this medication under this Patient Group Direction and agree to supply this medication in accordance with this Patient Group Direction

Name of Health Professional	Job Title	Signed	Date

Appendix 1

NHS Scotland Patient Group Direction For The Supply Of Varenicline (Champix ®) By Community Pharmacists

Authorisation
This Patient Group Direction give authority for:

(PRINT NAME of APPROVED PHARMACIST)

To supply varenicline (Champix ®) 0.5mg and 1mg to clients
(PHARMACY)

Requirements for a participating pharmacist

- To have satisfactorily completed any approved training;
- To have indemnity insurance;
- To maintain clinical knowledge appropriate to their practice by attending relevant study days, courses and to make themselves aware of appropriate current literature;
- To act as an approved practitioner within the terms of the Patient Group Direction and to supply accordingly.

I have received, read and fully understand my Health Board's policy on patient group directions.

I have received the training which approved practitioners must undertake before being authorised to supply varenicline under the relevant patient group direction.

I agree to act within the terms of the patient group direction and proforma and to supply accordingly.

I understand that by agreeing to act under the patient group direction and service level agreement I am adjusting my scope of professional practice.

Pharmacist's Signature: _____ **Date:** _____

Appendix 2

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 3

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)

NHS Borders Patient Group Direction for the Supply of Varenicline by Authorised Community Pharmacists.

Authorisation
These Patient Group Directions give authority for:

(PRINT NAME of APPROVED PHARMACIST)