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

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Supply of varenicline

Varenicline may be supplied as part of the National Public Health Service (PHS) element of the community pharmacy contractual arrangements to support quit attempts where the pharmacist has completed the Patient Group Direction (PGD) training relevant to this product. The monthly payments associated with supply in this way will be made through the national service Payment schedule. Varenicline must be supplied using the approved stationery.

A client can be considered for either NRT or varenicline, along with support from a recognised stop smoking service, following discussion of both options taking cognisance of the client's preferred choice and their suitability for treatment.

Varenicline must be supplied along with weekly support.

The client must be assessed for varenicline suitability before being signed up to the service.

The client must be appraised of the need for them to provide some basic medical information to allow the pharmacist to make an informed assessment of the suitability of the client to receive varenicline.

The client should be informed of the risks and benefits of using varenicline to support a smoking cessation attempt in order that the client can make an informed decision.

Pharmacist training

Varenicline can ***only*** be supplied by a pharmacist who has undertaken the associated training. Medicine counter staff must be trained to refer each request for varenicline to that pharmacist. The pharmacist must have successfully completed training approved by NES Pharmacy or the local health board. On-going behavioural support may be provided as usual by staff normally involved in smoking cessation support. NES training on "Varenicline Supply under PDG" is available online at via the Turas Portal

Premises

- The service should be provided from a suitable consultation area in the pharmacy: ideally a consultation room or else a quiet area within the pharmacy if a room is not available.

Patient Confidentiality

General Medical Council statement:

"Patients are entitled to expect that the information about themselves or others which a doctor learns during the course of a medical consultation, investigation or treatment, will remain confidential.

Any explicit request by a patient that information should not be disclosed to particular people, or indeed to any third party, must be respected save in the most exceptional circumstances, for example where the health, safety or welfare of someone other than the patient would otherwise be at serious risk"

Pharmacists *and their staff* must respect this duty of confidentiality and information should not be disclosed to any third party without the client's consent.

Referral

Pharmacists and pharmacy support staff can refer to other support services including Smoking Cessation Services and the patient's GP.

Adverse Drug Reaction (ADRs)

The Medicines and Health Products Regulatory Agency (MHRA) asks that all suspected serious reactions are reported through the Yellow Card Scheme. An adverse reaction should be reported even if it is not certain that the drug has caused it, or if the reaction is well recognised, or if other drugs have been given at the same time.

Report ADRs on line at: **www.yellowcard.gov.uk**

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Indication	Clients accessing the pharmacy smoking cessation service who wish to stop smoking. In NHS Lanarkshire Varenicline and Nicotinell Patches are both preferred choices on the Formulary. Product choice should be determined by patient circumstance and professional judgement.
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.
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.
Informed Consent	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.
Records	□ 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 3 for example letter); □ Severe adverse reactions should be reported to the MHRA using the 'Yellow Card' reporting system

References	□ British National Formulary (BNF) □ Summary of Product Characteristics (SPC) for Champix®. https://www.medicines.org.uk/emc/medicine/19045 Accessed February 2017 □ 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

Appendix 1

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

Authorisation
This Patient Group Direction give authority for:

Name of Pharmacist	
GPhC registration Number	
Name and address of the Pharmacy where you work most often	
Pharmacy contractor Code	
Signature	
Date	

to supply varenicline to suitable patients.

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 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)