Patient Group Direction

For the Supply of Varenicline (Champix®) By Authorised Community Pharmacists

This Patient Group Direction (PGD) is a specific written instruction for the supply of varenicline to groups of patients who may not be individually identified before presentation for treatment.

This will enable the appropriate registered healthcare professional to supply/administer treatment in accordance with the following protocol, the recommendations of the Department of Health 1998, the codes and standards of conduct of their professional bodies and any guidelines issued by those bodies on the supply and administration of medicines.

The majority of clinical care should be provided on an individual, patient specific basis. The supply of medicines under Patient Group Directions should be reserved for those limited situations where this offers an advantage for patients care (without compromising patient safety) and where it is consistent with appropriate professional relationships and accountability.

Supply of Varenicline

Varenicline can be supplied as part of the National Public Health Service (PHS) contract to support smoking cessation quit attempts, by pharmacists competent to offer this service. The monthly payments associated with supply in this way will be made through the national scheme using the Universal Claim Form. Varenicline must be supplied using a CPUS prescription to document the supply. Varenicline is first line choice for pharmacological support of smoking cessation attempts in NHS Tayside.

The client must be assessed for suitability of varenicline using the proforma attached to this PGD. Use of varenicline must always be combined with behavioural support to achieve the best chance of a successful quit. Pharmacists should discuss varenicline therapy with the client taking cognisance of the client's preferred choice, their best chance of success and their suitability for treatment. Varenicline must be supplied along with weekly behavioural support.

The client must be appraised of the need for them to provide some basic medical information to allow the pharmacist to determine how best to help them with their smoking quit attempt. In common with all medicines provided by a pharmacist, 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.

Definition of clinical situation/condition	Clients who wish to stop smoking, accessing smoking cessation services offered by pharmacists
Name of organisation(s) within which the PGD will operate	NHS Tayside community pharmacies contracted to supply services to NHS Tayside. Health care provided in the Scottish Prison Service.
Name(s) of clinical areas and locations where the PGD will operate	All community pharmacies contracted to supply services to NHS Tayside. Scottish Prison Service. All care environments where patient access smoking cessation support from pharmacists
Criteria for inclusion	• Varenicline is indicated for smoking cessation in adults • Clients over 18 years of age The client agrees to receive ***behavioural support*** according to the agreed protocol
Criteria for exclusion	• 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.
Action if excluded	Refer to GP or seek advice from the Specialist Smoking Cessation Service. Patients who are excluded from the use of varenicline may be suitable for smoking cessation support using NRT.
Action if patient declines	Discuss alternative products if suitable and/or seek advice from the Specialist Smoking Cessation service (01382 424127)
Follow up of patient	Patients should receive weekly behavioural support from staff trained to provide this in the pharmacy.

Caution	• Physiological changes resulting from stopping smoking, 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 and insulin, clozapine). As smoking induces CYP1A2, smoking cessation may result in an increase of plasma levels of CYP1A2 substrates. • Changes in behaviour or thinking, anxiety, psychosis, mood swings, aggressive behaviour, depression, suicidal ideation and behaviour and suicide attempts have been reported in patients

	attempting to quit smoking. Pharmacists should be aware of the possible emergence of serious neuropsychiatric symptoms in patients attempting to quit smoking with or without treatment. If neuropsychiatric symptoms occur whilst on varenicline treatment, patients should discontinue varenicline immediately and contact doctor for assessment. • Renal impairment < 30mls/min. Consider renal function in elderly patients. • Conditions that lower the seizure threshold • PMR indicates patient is unsuitable for varenicline • There have also been post-marketing reports of rare but severe cutaneous reactions, including Stevens-Johnson Syndrome and Erythema Multiforme in patients using varenicline. As these skin reactions can be life threatening, patients should discontinue treatment at the first sign of rash or skin reaction and contact their doctor. • Patients stopping smoking can experience new or worsening cardiovascular symptoms. Patients 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

Characteristics of staff authorised to take responsibility for the supply or administration of medicines under this patient group direction

Profession	Pharmacist
Applicable professional codes and standards of conduct	The current GPhC Standards of Conduct, Ethics and Performance
Applicable guidelines for supply and administration of medicines	None, but guiding principles laid out in the above document

Providing Varenicline in a Pharmacy

Varenicline must be supplied by a pharmacist who is competent to offer care under this PGD. However the associated behavioural and peer support may be provided by a range of trained staff. Medicine counter staff should be supported to encourage the use of varenicline for clients seeking smoking cessation support.

Indemnity

The pharmacist must ensure that the organisation that provides their professional indemnity has confirmed that this activity will be included in their policy.

Clinical Support

The accredited pharmacist will not be working in isolation and must feel confident to refer to other sources of information and support services including Smoking Cessation Services and the patient's GP. The pharmacist is expected to participate in appropriate clinical governance activities that enable reflection on their practice.

DESCRIPTION OF TREATMENT AVAILABLE UNDER THIS PATIENT GROUP DIRECTION

Name of Medicine	Varenicline (Champix®) Tablets
POM/P/GSL	POM
PGD Ref No	
Dose/s	500 mcg and 1mg film coated tablets
Route	Oral
Total dose number	**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 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. For patients who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment with varenicline at 1 mg twice daily may be considered for the maintenance of abstinence. A gradual approach to quitting smoking with varenicline

	should be considered for patients who are not able or willing to quit abruptly. Patients should reduce smoking during the first 12 weeks of treatment and quit by the end of that treatment period. Patients should then continue taking varenicline for an additional 12 weeks for a total of 24 weeks of treatment. Patients who are motivated to quit and who did not succeed in stopping smoking during prior varenicline therapy, or who relapsed after treatment, may benefit from another quit attempt with varenicline. In smoking cessation therapy, risk for relapse to smoking is elevated in the period immediately following the end of treatment. In patients with a high risk of relapse, dose tapering may be considered.
Advice to be given to the patient	Side-effects can include: • Nausea • Sleep disorders/ abnormal dreams • Headache • Appetite changes • Dry mouth /taste disturbances • Drowsiness • Dizziness Please refer to BNF and SPC for full list. 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 major reasons for varenicline failure are: - Unrealistic expectations; - Lack of preparation for the fact that tablets may cause nausea; - Insufficient support from trained smoking cessation advisor It is important to make sure that the client understands the following points: 1. Varenicline is not a magic cure: effort and determination are crucial 2. Varenicline works by acting on the parts of the brain

	which are affected by nicotine in cigarettes 3. Varenicline does not remove all the temptation to smoke, but it does make abstinence easier (it takes the edge of 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. 4. Varenicline is safe, but about a third of clients may experience mild nausea usually about 30 minutes after taking it. This reaction often diminishes gradually over the first few weeks, and most patients tolerate it without problems; 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 which can be addressed through diet and exercise • 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 advise the patient about this.
Identification and management of possible adverse effects	Smoking cessation with or without treatment is associated with various symptoms. For example, dysphoric or depressed mood; insomnia, irritability, frustration or anger; anxiety; difficulty concentrating; restlessness; decreased heart rate; increased appetite or weight gain have been reported in patients attempting to stop smoking. Studies have not distinguished between the adverse effects experienced because of nicotine withdrawal and those associated with varenicline. A list of adverse effects and there relative frequency can be found in the SMPC for Champix https://www.medicines.org.uk/emc/product/266/smpc#PRODUCTINFO
Referral for medical advice	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.

Treatment Records	• Patient's name, address, date of birth and GP details; • Date supplied & name of the pharmacist who supplied the medication; • Reason for inclusion; • Advice given to patient; • Details of any adverse drug reaction and actions taken including documentation in the patient's medical record via GP; • All adverse reactions should be reported to the CHM using the 'Yellow Card' reporting system • The varenicline clinical risk assessment form should be completed for each client and retained in the pharmacy for a minimum of 3 years.
Patients on concurrent medication	No clinical meaningful drug interactions have been reported. Since metabolism of varenicline represents less than 10% of its clearance, active substances known to affect the cytochrome P450 system are unlikely to alter the pharmacokinetics of varenicline and therefore a dose adjustment of varenicline would not be required
Patient 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 the NHS Scotland to ensure proper record keeping and patient safety.
Adverse Reactions	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. However, smoking cessation / nicotine withdrawal itself is associated with low mood / changes to mental state. Clients taking medications that may be affected when they stop smoking should be advised to tell their prescriber of their quit attempt. All adverse reactions (actual and suspected) will be reported to the appropriate medical practitioner and

	recorded in the appropriate place (e.g. the Minor Injury Record Sheet or the Allergies and Adverse Reactions section of the General Practice Record). Where appropriate a Yellow Card Report will be forwarded to the Committee on Safety of Medicines. A supply of these forms can be found at the rear of the British National Formulary. Online reporting is available at http://yellowcard.mhra.gov.uk/
Adverse Incidents	All adverse incidents such as incorrect dose, dispensing errors, pregnancy coming to light after treatment has started, overdose, etc should be reported via the pharmacy's own in-house governance mechanism and accurately documented in the patient's PGD records

AUDIT OF PATIENT GROUP DIRECTION

Annual audit of documentation and recording of information - Who will carry this out and to whom will it be reported?	Pharmacists using this PGD should carry out an annual audit of activity using this PGD. A documentation audit should sample completeness of documentation
Periodic audit of clinical outcome(s) - How often will audit be carried out? - What are the audit questions? - Who will carry out the audit(s) - To whom will the audit be reported?	The clinical outcomes associated with the performance of each pharmacy in Tayside in smoking cessation are available from the Health Board. Pharmacists can obtain the data for their pharmacies and compare to local and national benchmarks

MANAGEMENT & MONITORING OF PATIENT GROUP DIRECTION

Developed By:

Medical Practitioner: Signature:

Nurse: Signature:

Pharmacist: Signature:

Tayside Area Drug & Therapeutics Committee

Name: Signature:

Date Effective:

Review Date:

Plans must be made to ensure completion of a review on or by the date above. The revised PGD will then follow on immediately. Interim review will be required as and when new safety information comes to light.

Authorisation to Supply Varenicline

These Patient Group Directions 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 the approved training:
- To have been accredited as an approved practitioner within this scheme
- To have been advised 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 Proforma and to supply accordingly
- To work in an approved pharmacy

Authorising signature

Date

- 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 as an approved practitioner within the terms of the patient group direction and proforma and to supply accordingly
- I understand that by agreeing to act as an approved practitioner under the patient group direction and service level agreement I am adjusting my scope of professional practice

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

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 <u>reverse</u> order to facilitate tapered discontinuation.

Pharmacy Stamp

Client name:
Address:

Telephone number:
Date of birth:
GPs name & address:

Varenicline Patient Assessment Form

Factor	Yes	No	Notes
Is client under 18 years of age			If ' yes' – refer / consider NRT
Is client pregnant or breastfeeding?			If ' yes' – refer`/ consider NRT
Does client suffer from significant renal impairment or end stage renal disease?			If ' yes'- refer / consider NRT
Does client have a history of significant diagnosed psychiatric illness (Refer to PGD)			If ' yes' – refer / consider NRT
Is Patient currently prescribed Clozapine?			If 'yes' – refer to G.P.
Does client suffer from a lowered seizure threshold or epilepsy?			If ' yes' – refer / consider NRT
Is client currently on another smoking cessation therapy?			If ' yes' – counsel patient about the way varenicline works
Is client on any other medication?			Please consult PGD and relevant information source
Is client hypersensitive to varenicline or any of its excipients?			If ' yes' - refer

Action taken:
Supply:

Referral to:

Advice given:

The above information is correct to the best of my knowledge. I have been counselled on the use of varenicline and understand the advice given to me by the pharmacist. **Client's signature:** Date	The action specified was based on the information given to me by the client, which, to the best of my knowledge, is correct **Pharmacist's signature:** Date:

Date:

Dear Dr

Patients Name:

Address:

DOB / CHI:

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 normal length of treatment on this medicine is 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)