PATIENT GROUP DIRECTION FOR THE SUPPLY OF VARENICLINE 500 micrograms AND 1mg TABLETS (CHAMPIX®) FOR SMOKING CESSATION BY AUTHORISED COMMUNITY PHARMACISTS WORKING IN NHS LOTHIAN

MANAGEMENT OF PATIENT GROUP DIRECTION

This Patient Group Direction must be read, agreed to and signed by all healthcare professionals involved in its use. The original signed copy should be held by a designated person and must be easily accessible to healthcare professionals in the clinical setting. In all cases the healthcare professional will follow the code of conduct as defined by their professional body.

	Name	Signature	Date
Developed by LOCAL DEVELOPMENT TEAM			
Doctor	Dr Ewen Stewart		
Pharmacist	Maureen Reid		

Approved by PGD SUB-GROUP OF THE MEDICINES POLICY COMMITTEE			
Chairperson	Garry Todd		

Approved by AUTHORISED NHS LOTHIAN DRUGS AND THERAPEUTICS COMMITTEE			
Chairperson/Deputy of Committee	Dr Simon Maxwell		

AUTHORISED BY			
Medical Director	Ms Tracey Gillies		

LOCAL MANAGEMENT			
Practice/Ward/Department/Directorate			
Clinical Lead			
Practitioner Manager (if applicable)			
Pharmacist (if applicable)			
Name of Designated PGD Holder (Responsible for ensuring names of healthcare professionals issuing under this PGD are kept up to date			

DATE AUTHORISED FOR USE	REVIEW DATE	EXPIRY DATE
24/09/2020	24/09/2022	24/09/2023

Contractor Code/ Locum:

AUTHORISED PRACTITIONER LIST:

I have read and understood the Patient Group Direction and agree to use it and acknowledge that it is my responsibility to maintain my knowledge, skills and competencies through CPD.

Name	Signature	GPhC Number	Date

1. CHARACTERISTICS OF STAFF	
Define Practitioner Group	Community Pharmacist
Qualifications Required	Current GPhC Registration
Additional requirements	▪ To have satisfactorily completed the training approved by NES Pharmacy or NHS Lothian to include appropriate training for working under PGDs for the supply and administration of medicines. ▪ To have been accredited as an approved practitioner within this scheme ▪ To have indemnity insurance ▪ To act as an approved practitioner within the terms of the Patient Group Direction of the NHS Board and Proformas and to supply accordingly ▪ To work in an approved pharmacy ▪ Able to assess the person's capacity to understand the nature and purpose of the medication in order to give or refuse consent
Continued training requirements	▪ To maintain clinical knowledge appropriate to their practice by attending relevant study days, courses and to make themselves aware of appropriate current literature

2. DESCRIPTION OF TREATMENT	
Names of Medicines included	Varenicline (Champix®) Tablets
Marketing Authorisation (previously UK Product Licence)	YES
Outwith terms of the Summary of Product Characteristics	NO
2nd Pharmacist Check	YES Dawn Owen
Controlled Drugs **If YES, consultation with CDGT to check legal compliance**	NO
Antibiotic **If YES, consultation with Microbiologist/Antimicrobial Management Team**	NO
Children under 13 years of age to be treated **If YES, consultation with Neonatologist, Paediatrician, Public Health or Unscheduled Care**	NO
Record / Audit trail	▪ 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. ▪ The varenicline clinical risk assessment form should be completed for each client and retained in the pharmacy for a minimum of 3 years. (see appendix II) ▪ The GP should be made aware of the prescription and asked to make a record of this on the patients record (see sample letter appendix III) ▪ Details of any adverse drug reaction and actions taken including documentation in the patient's medical record via GP.

3. MEDICINES and CLINICAL CONDITION	
Name of medicine	Varenicline (Champix®) Tablets
Define situation/condition	Clients accessing the pharmacy smoking cessation service who wish to stop smoking .
Criteria for inclusion (including patient group)	▪ 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 agreed to receive behavioural support according to the agreed protocol. ▪ A full medical history is taken and documented and there are no contraindications or cautions for treatment with varenicline. ▪ No indication on the PMR that the patient is unsuitable for varenicline.
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. ▪ Patients with a major psychiatric disorder (depression, schizophrenia, anxiety or panic disorder) who have experienced a significant worsening of their condition in the last six months requiring hospitalisation or a change or increase in their psychiatric medication. ▪ Patients with a psychiatric disorder who have not been stable on their medication for the last 3 months ▪ End-stage renal disease ie dialysis. ▪ History of seizures eg epilepsy or conditions where seizure threshold may be lowered. ▪ Patients known to be using other smoking cessation aids. ▪ Informed non consent
Action if excluded	▪ Refer to GP for further assessment ▪ Discuss alternative products if suitable
Action if patient declines	Discuss alternative products if suitable and/or offer a referral to the Specialist Smoking Cessation service for further assessment and smoking cessation support.
Pharmaceutical form and strength of medicine	▪ Varenicline (Champix®) 500 micrograms tablets ▪ Varenicline (Champix®) 1mg tablets
POM / P / GSL / ▼	POM

Dose/s	**Days 1-3:** 500 micrograms (white tablets) once daily **Days 4-7:** 500 micrograms tablets twice daily **Day 8 to the end of the treatment:** 1mg (blue tablets) twice daily for 11 weeks. (reduce to 500 micrograms twice daily if not tolerated) Patients who cannot tolerate the adverse effects of varenicline may have the dose lowered temporarily or permanently to 500 micrograms twice daily.
Route/Method	Oral
Frequency **(To include maximum/minimum timescales)**	▪ 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. **<u>Treatment Regime</u>** **1st Consultation (Assessment)** ▪ Client should set a quit date between the next 8-14 days. Supply 14 day starter pack (11 x 500 micrograms tablets with 14 x 1mg tablets). ▪ Set a formal quit date between one and two weeks after starting varenicline. ▪ Take a carbon monoxide reading. **2nd Consultation (Before quit date)** Confirm quit date. Monitor and record carbon monoxide reading. Supply 1mg varenicline tablets as required. **3rd Consultation (First follow up)** Monitor and record carbon monoxide reading and confirm abstinence. Supply varenicline tablets as required (refer to Appendix 1). **Subsequent Consultations** Supply varenicline tablets if patient has stopped smoking and carbon monoxide reading confirms abstinence (Refer to Appendix 1). **Final Consultation (week 10-12)** Discuss coping strategies when the support service finished. Supply varenicline tablets (if required) if patient has stopped smoking and carbon monoxide reading confirms abstinence (refer to Appendix 1).
Total dose/number	See above

Drug interactions and action to be taken	▪ 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. ▪ 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. ▪ Refer to Appendix 1 of BNF for latest information on interactions
Cautions (including action to be taken if caution applies)	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 as additional monitoring will be required. Patients on insulin should be advised to monitor their blood glucose levels more closely and contact their GP or specialist diabetes service if glucose levels change Patients with a history of serious psychiatric illness such as schizophrenia, bipolar disorder or major depressive disorder currently receiving treatment and/or pharmacotherapy. 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. 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.
Adverse reactions and side effects including actions to be taken if adverse drug reaction is suspected (▼ - include yellow card details)	▪ Nausea ▪ Sleep disorders/abnormal dreams ▪ Headache ▪ Appetite changes ▪ Dry mouth/taste disturbances ▪ May cause dizziness, somnolence and transient loss of consciousness, 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. ▪ For less common side effects please refer to BNF ▪ Varenicline should be discontinued immediately if agitation, depressed mood or changes in behaviour that are of concern for the pharmacist, patient's family or caregiver are observed or if the patient develops suicidal thoughts or suicidal behaviour. ▪ Patients who cannot tolerate the adverse effects of varenicline may have the dose lowered temporarily or permanently to 500 micrograms twice daily. ▪ If client experiences any extreme side effects they should seek medical advice. ▪ Any adverse events that may be attributable to varenicline should be reported to the Commission on Human Medicines (CHM) via the Yellow Card Scheme via http://yellowcard.mhra.gov.uk/ ▪ Details of any adverse drug reaction and actions taken should be documented in the patient's medical record via GP.

Additional advice and information	▪ Advice to clients should include specific product advice on dosage, method of administration and side effects. ▪ Tablets should be swallowed whole with plenty of water and can be taken with or without food. ▪ 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: - Varenicline is not a magic cure: 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 off the discomfort by reducing the severity of tobacco withdrawal symptoms such as craving to smoke, irritability, poor concentration and low mood). - 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. ▪ Advise on follow-up and obtaining further supplies. ▪ 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. ▪ Patients should be advised to discontinue treatment and seek prompt medical advice if they develop agitation, depressed mood, or suicidal thoughts. Patients with a history of psychiatric illness should be monitored closely while taking varenicline. ▪ If the patient continues smoking for 2 weeks after the set quit date, varenicline should be stopped. ▪ Advise on effects on driving or using machinery. ▪ Patients on insulin should monitor blood glucose closely ▪ 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. ▪ Advise to contact nurse/GP if condition worsens or symptoms persist - Manufacturers Patient Information Leaflet should be offered.

Referral, patient monitoring and follow-up	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. Pharmacists should refer clients to their GP when client is considered eligible for varenicline but they have any of the following: ▪ Previously unrecognosed co-morbidities ▪ Patients on theophylline due to monitoring that is required ▪ Patients on warfarin ▪ Patients on antipsychotics ▪ Patients with renal failure See Appendix 1 – Treatment Plan for patient monitoring and follow up. Also see "Frequency" section above.

4. REFERENCES

1. Summary of Product Characteristics (SPC) for Champix® last accessed 24/09/2020 via http://www.medicines.org.uk

2. eBNF last accessed 24/09/2020 via http://www.bnf.nice.org.uk

3. National Institute for Health and Clinical Excellence. Varenicline for smoking cessation. NICE technology appraisal 123, July 2007.

4. Medicines and Health Product Regulatory Agency (MHRA) safety alert: November 2008.

5. https://www.gov.uk/drug-safety-update/varenicline-and-suicidal-behaviour-cohort-study-provides-some-reassurance

6. 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. http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)30272-0/abstract (accessed June 2016)

5. APPENDICES

Appendix I – Treatment Plan

Appendix II – Varenicline Clinical Risk Assessment Form

Appendix III – Sample GP letter

Appendix IV – General Guidance

Appendix I

Treatment Plan

Consultations	Treatment Plan
1st week – Assessment week	Assess if client committed to setting a quit date between the next 8-14 days. If YES - Supply 14 day starter pack (11 x 500microgram tabs with 14 x 1mg tablets). If NO – refer to stop smoking service for pre quit support. Make arrangements to see client again before tablets run out, i.e. between days 7-14. Confirm quit date and enter onto the Pharmacy Care Record (PCR)
3rd week	Establish if client achieved quit date. Monitor and record 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 (week 4). Record on PCR
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. Record on PCR 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 or reduced. 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 500microgram 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. Discuss coping strategies for nicotine cravings when the support service has finished. Record on PCR

Appendix II

Varenicline Clinical Risk Assessment Form

Pharmacy Stamp	Client name: Address: Telephone number: Date of birth: GPs name & Address:

Factor	Yes	No	Notes
Is client under 18 years of age			If 'yes' -*refer
Is client pregnant			If 'yes' -* refer
Is the client breastfeeding			If 'yes' -* refer
Does client have end stage renal disease?			If 'yes' -* refer or offer NRT
Does client have a history of serious or unstable psychiatric illness or on clozapine			If 'yes' *- refer
Does client suffer from epilepsy?			If 'yes' -* refer
Is client currently on another smoking cessation therapy?			If 'yes' -* refer
Is client on any other medication?			Please list. Check PGD for interaction and cautions. Advise re importance of monitoring
Is client hypersensitive to varenicline or any of its excipients?			If 'yes' - *refer

*GP, CPN, psychiatrist or specialist service as appropriate

Special circumstances and any other relevant notes:

Only make a supply if you are certain that to the best of your knowledge, it is appropriate to do so.

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:

Appendix III

Pharmacy Stamp

Date:

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 12 weeks.

Please add this medicine to the patient's medication records. No further action would be required from you, as the patient will 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)*

Appendix IV

GENERAL POLICY FOR COMMUNITY PHARMACIST SUPPLYING VARENICLINE (CHAMPIX®)

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.

"Only individuals who are registered healthcare professionals and are allowed to supply prescription only medicines using a PGD are able to use this process. The clinical decision to supply varenicline using the PGD remains with the registered healthcare professional and must not be directed by other healthcare workers".

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 is joint first line with NRT in NHS Lothian.
Varenicline must be supplied along with weekly support.

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

The client must be appraised of the need for them to provide 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.

The client should be informed that their GP will be informed of the treatment.

Pharmacists 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 is available online at: **https://learn.nes.nhs.scot/Scorm/Launch/1475**

Premises

The service can only be provided in a pharmacy, which must have a suitable area for consultation with patients. This should be a consultation room (or quiet area within the pharmacy if a room is not available).

Indemnity

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

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.

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.

Adverse Drug Reaction (ADRs)

The Medicines and Health Products Regulatory Agency (MHRA) asks that all suspected reactions (including those not considered to be serious) 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**

Details of Treatment Course

See appendix I – Treatment Plan and PGD

Quantity to supply at one time
In exceptional circumstances, discretion may be used in the number of days' treatment supplied if for example a patient is planning to go on holiday or away on business. It would be good practice to annotate the PCR stating the reason when (other than the starter pack) more than 7 days' supply is given.

Advice to Patients
The major reasons for varenicline failure are:

- Unrealistic expectations
- Lack of preparation for the fact that tablets may cause nausea

Pharmacists should discuss with the patient about the need for motivation to quit. It is also good practice to ensure that the patient is aware of the following:

- Successful varenicline therapy requires patient motivation to stop smoking.
- Varenicline works by acting on receptors in the brain which are affected by the nicotine in cigarettes
- Varenicline does not remove all the temptation to smoke, but it does make abstinence easier
- Around a third of patients 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;

Dose adjustment for side effects
Patients (particularly the elderly) may find that the side effects of varenicline are intolerable after they have increased their varenicline dose to 1mg twice daily.
It is possible that therapeutic plasma levels of varenicline are achieved with a lower dose.
So reduce the dose to 0.5mg tablets twice daily.
Be aware that some patients having found varenicline therapy beneficial but unable to face the side effects might make their own decision to reduce their dose to 1mg once a day. However, a twice daily regimen is better.

Patients with Renal Conditions
Varenicline is cleared through the kidneys. It follows that patients with end stage renal disease may not adequately clear the drug. Moreover there are no supporting data for use of varenicline in this group, so it should not be prescribed.
However, patients with less severe renal disease may be prescribed varenicline. If a patient describes kidney problems, refer to the GP for details of their condition.
The patient may build up higher plasma levels of the drug and suffer more side effects.
As with all patients they may be prescribed a lower dose if they do not tolerate the recommended dose.
Refer to section 4.2 of the varenicline SPC for further details[2]
https://www.medicines.org.uk/emc/medicine/19045

Patients with Severe Mental Health Conditions
Diagnosis of severe mental health conditions can be difficult by the nature of the illness and might often only be made after a period of watchful waiting.
A major depressive disorder can encompass a spectrum of symptoms and should not be confused with mild or moderate depression. For the purposes of the PGD it might be simplified as a patient whose depression has required psychiatric intervention. Typically the patient will be managed by a psychiatrist and might have a CPN assigned to them.
Pharmacists should be mindful that many such patients may have been stable for a long time, and their diagnosis doesn't mean they aren't suitable for varenicline. If this is a consideration, community pharmacists are asked to contact the GP or psychiatry team for discussion and advice before making a supply.
The recent EAGLES study[3] has provided evidence that there is no association with the use of varenicline and an increased risk of serious neuropsychiatric adverse events compared with placebo.

Patients with Epilepsy
The varenicline SPC[2] states that 'In clinical trials and post-marketing experience there have been reports of seizures in patients with or without a history of seizures, treated with Champix®. It should be used cautiously in patients with a history of seizures or other conditions that potentially lower the seizure threshold'. Refer these patients to their GP. While they are excluded from the PGD, their GP may be able to conduct a more thorough clinical risk assessment of the patient and subsequently prescribe.

References
1. NHS Scotland National Template Patient Group Direction for the supply of Varenicline (Champix®) by Authorised Community Pharmacists working in Scotland

2. Champix® eSPC https://www.medicines.org.uk/emc/medicine/19045 (accessed September 2020)

3. 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.
http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)30272-0/abstract
(accessed June 2016)