PATIENT GROUP DIRECTION

FOR THE SUPPLY OF VARENICLINE ▼ (CHAMPIX®) TO ADULTS OVER 18 YEARS OF AGE BY COMMUNITY PHARMACISTS UNDER THE PUBLIC HEALTH SERVICE - SMOKING CESSSATION SERVICE IN NHS HIGHLAND

THE COMMUNITY PHARMACIST SEEKING TO SUPPLY VARENICLINE MUST ENSURE THAT ALL PATIENTS HAVE BEEN SCREENED AND MEET THE CRITERIA BEFORE SUPPLY TAKES PLACE

NHS Highland has authorised this patient group direction to help patients by providing them with more convenient access to an efficient and clearly defined service within NHS Highland. It cannot be used until Appendices 4 & 5 are completed for each clinical area

Warning- Document uncontrolled when printed

Further information on the use of Patient Group Directions in NHS Highland and the PGD procedure can be obtained from

http://intranet.nhsh.scot.nhs.uk/Organisation/ADTC/PGDSG

PATIENT GROUP DIRECTION FOR THE SUPPLY OF VARENICLINE ▼ (CHAMPIX®)

Management and monitoring of patient group direction

Prepared by:	
Medical Practitioner	Name: Dr Hugo van Woerden Title: Director of Public Health Signature ...
Senior representative of the professional group who will provide care under the direction.	Name: Ian Rudd Title: Director of Pharmacy Contact details: Pharmacy Services, NHS Highland, John Dewar Buliding, Inverness IV2 7GE Telephone: 01463 706886 Fax: 01463 713844 Signature .....
Pharmacist	Name: Mary Morton Title: Head of Community Pharmaceutical Services Signature .....
Authorised by:	
Patient Group Direction Sub-group Chair or Secretary	Name: Mark Smith Title: Secretary of the PGD Subgroup Signature..... ASSOCIATE LEAD NURSE
Date of ratification of the direction on behalf of the Area Drug & Therapeutics Committee	Date: 13 May 2016
Review Date	Two years from final ratification and every three years thereafter. Or when there is a change in clinical practice, evidence or the Summary of Product Characteristics for any of the medicines included is updated, whichever is first.

Clinical indication to which this patient group direction applies

Definition of situation/condition	Patients accessing the community pharmacy smoking cessation service who must have tried to stop through a recognised service using nicotine replacement therapy (NRT) with motivational support.
Clinical criteria for inclusion	• Dependent smoker (i.e. they smoke within 30 minutes of waking up and /or find quitting unaided difficult) identified as sufficiently motivated to quit • Patients over 18 years of age • The patient agrees 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 (see criteria for exclusion and referral) • No indication on the patient medication record (PMR) that the patient is unsuitable for varenicline
Clinical criteria for exclusion	• Smokers not sufficiently motivated to quit • Patient under 18 years of age • Pregnant or breastfeeding women • Sensitivity to varenicline or any of its excipients • Renal impairment where the glomerular filtration rate (eGFR) is less than 30mL/minute/1.73m^2 (use with caution in elderly patients) • History of cardiovascular disease • Epilepsy • Not to be used in conjunction with other smoking cessation therapies • PMR indicates that the patient is unsuitable for varenicline
Criteria for seeking further clarification from doctor	• Renal impairment of unknown severity • Reported history of cardiovascular disease
Caution	Patients on insulin may be supplied with varenicline but must be advised to monitor their blood glucose levels closely. Cessation of smoking may increase the blood levels of some drugs, e.g. theophylline.
Action if patient excluded from treatment	Refer patient to Specialist Smoking Cessation Service or general practitioner. The reason why the patient was excluded under the PGD will be documented in the PMR.
Action if patient declines treatment	Discuss alternative products if suitable and/or offer referral to the Specialist Smoking Cessation Service for further assessment. The reason why the patient declined treatment under the PGD will be documented in the PMR.

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

Qualifications required	Pharmacist registered with the General Pharmaceutical Council.
Initial training	The pharmacist must have successfully completed training approved by NES Pharmacy and NHS Highland. Received and understood training to undertake the supply of medicines under a PGD and must be familiar with the content of the NHS Highland PGD PowerPoint presentation. Has undertaken appropriate training to carry out clinical assessment of patients leading to a diagnosis that requires treatment according to the indications listed in the PGD.
Competency assessment	Varenicline must only be supplied by an accredited pharmacist who must provide evidence to NHS Highland of having successfully completed training approved by NES Pharmacy and additional NHS Highland events.
Ongoing training and competency	• The Pharmacist is expected to attend any additional training sessions organised by NHS Highland on an on-going basis. • Maintenance of own level of updating with evidence of continued professional development

Description of treatment available under the patient group direction

Name, form & strength of medicine	Varenicline ▼ (Champix®) 500mcg and 1mg tablets
Legal status	**POM**
Indicate any off-label use (if relevant)	Not applicable
Route/Method of Administration	Oral
Frequency of dose/ duration of treatment	• **Days 1 - 3:** • One 500 micrograms (white) tablet daily • **Days 4 – 7:** • One 500 micrograms (white) tablet twice daily • **Day 8 to the end of the treatment:** • One 1 mg (blue) tablet twice daily for 11 weeks. (Reduce to one 500 micrograms twice daily if not tolerated) • Maximum single dose 1 mg • Maximum daily dose 2 mg • Patient should set a date to stop smoking. Patient should start taking varenicline 1 to 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 micrograms twice daily. Every attempt should be made to reduce the use of varenicline to zero by the end of 12 weeks.
Quantity to be supplied	See Appendix 1 Treatment Plan.
Maximum or minimum treatment period	Treatment should not exceed 16 weeks
Follow up treatment	See Appendix 1 Treatment Plan. Varenicline must be supplied along with weekly support.
Written information to be given to the patient or carer	Provide supportive literature at the pre-quit assessment and encourage the patient to keep a smoking diary prior to returning. Patient should be encouraged to complete the relevant sections in the NHS Health Scotland Publication 'How to Stop Smoking and Stay Stopped' (http://www.healthscotland.com/documents/312.aspx) and bring back to the pharmacy at week one for discussion. Provide a patient information leaflet if varenicline is supplied.

Follow-up advice to be given to patient or carer	• Advice to patients should include specific product advice on dosage, method of administration and side effects • **If patient experiences any extreme side effects then varenicline should be discontinued immediately and prompt medical advice sought if agitation, depressed mood or changes in behaviour that are of concern for the pharmacist, patient's family or carer are observed or if the patient develops suicidal thoughts or suicidal behaviour** • 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 patient understands the following points: 1. Varenicline is not going to work without the crucial effort and determination of the patient. 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. 4. Varenicline is safe, but about 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. 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, • 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.
Identifying and managing possible adverse reactions	*Drug interactions* – No clinically meaningful drug interactions have been reported. *Side Effects* – Nausea, sleep disorders/abnormal dreams, headache, appetite changes, dry mouth/taste disturbances, drowsiness and dizziness. For less common side effects, please refer to BNF. Varenicline is a relatively new drug and thus carries a black triangle (▼). 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 adverse drug reactions (ADRs) on line at: **www.yellowcard.gov.uk**

Referral for medical advice	Appearance or suspicion of an adverse reaction, as above.
Facilities required	The service is only approved for pharmacies that have a suitable quiet area for consultation within the pharmacy, preferably a consultation room.
Special considerations/ additional information	Patients 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 (see Appendix 3) and NHS Scotland to ensure proper record keeping and patient safety.
Details of records required	• 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; • The varenicline clinical risk assessment form should be completed for each patient and retained in the pharmacy for a minimum of 3 years. • All adverse drug reactions should be reported using the "Yellow Card" reporting system.
References	• British National Formulary (BNF) 70, September 2015 – March 2016 • Summary of Product Characteristics (SPC) for Champix® accessed 7 March 2016. http://www.emc.medicines.org.uk. • National Institute for Health and Clinical Excellence. Varenicline for smoking cessation. NICE technology appraisal 123, July 2007. http://www.nice.org.uk/TA123 • Medicines and Health Product regulatory Agency (MHRA) safety alert: November 2008 http://webarchive.nationalarchives.gov.uk/20141205150130/http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON087901 • Public Health Services (PHS) – Smoking Cessation Service Revised Service Specification16 June 2014. http://www.sehd.scot.nhs.uk/pca/PCA2014(P)12.pdf

Appendix 1

Treatment Plan

Consultations	**Treatment plan**
Pre-quit attempt	Complete the patient assessment form, complete the Pharmaceutical Care Record (PCR). Discuss setting a formal quit date and the need to start varenicline around 7 days before this date. Do not set the quit date in the PCR at this stage. Arrange an appointment for the patient to see the pharmacist and receive a supply of varenicline and further support at least 7 days before the quit date. Provide support literature and encourage the patient to keep a smoking diary prior to returning at Week1.
Week 1	Patient should set a quit date between the next 8 to 14 days. Supply 14 day starter pack (11 x 500 micrograms tablets with 14 x 1 mg tablets) *Make arrangement to see patient again before tablets run out i.e. between days 10 to 14
Week 3	Patient should have set a quit date. Monitor carbon monoxide level. If patient is still smoking, he/she should be informed that treatment with varenicline would have to be stopped if he/she continued to smoke. Supply 1 mg varenicline tablets if required. Make arrangement to see patient the following week
Week 4 - 12	Monitor carbon monoxide level and check if patient has stopped smoking. **If patient is still smoking, treatment with varenicline should be stopped.** If patient has quit smoking supply 1 mg varenicline tablets as required. If side effects are tolerable then continue supplying varenicline 1 mg tablets as required**.** If patient 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 500 micrograms tablets with 14 x 1 mg tablets) 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

Varenicline Clinical Risk Assessment

Pharmacy Stamp

Patient name:
Address:

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

Form

Factor	Yes	No	Notes
Is patient under 18 years of age			If ' yes' - refer
Is patient pregnant or breastfeeding?			If ' yes' – refer`
Does patient suffer from renal impairment or has end stage renal disease?			If ' yes'- refer
Does patient have a history of psychiatric illness (Please refer to PGD)			If ' yes' - refer
Does patient suffer from epilepsy?			If ' yes' - refer
Is patient currently on another smoking cessation therapy?			If ' yes' - refer
Is patient on any other medication?			Please list. Check PGD for interaction
Is patient hypersensitive to varenicline or any of its excipients?			If ' yes' - refer
Does patient have a history of cardiovascular disease?			If ' yes' - refer

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. I have been informed that information relating to the supply of varenicline will be passed to my GP **Patient's signature:** Date:	The action specified was based on the information given to me by the patient, which, to the best of my knowledge, is correct **Pharmacist's signature:** Date:

Appendix 3

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 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)*

……..*(PRINT Pharmacy Name)*

……..*(Pharmacy phone number)*

Appendix 3

Date:

Dear Dr

Patient's name:

Address:

DOB:

I saw the above patient at the pharmacy today and I have completed the *Varenicline Clinical Risk Assessment Form* (attached) with a view to supplying varenicline tablets to help him/her give up smoking. The patient would be taking varenicline for a maximum of 12 weeks. As you will see on the form, the patient has answered "yes" to one or more questions, so I would be grateful if you could let me know if you think that it is suitable for the patient to be prescribed varenicline by myself. If so, 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)*

……..*(PRINT Pharmacy Name)*

……..*(Pharmacy phone number)*

Appendix 4

Health professionals approved to provide care under the direction

To be retained in the community pharmacy as a record of those pharmacists who have signed the PGD.

An Individual Authorisation Form (Appendix 5) should be completed and returned to the Pharmacy Services Office

The **lead professional** of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The **manager** who approves a healthcare professional to supply and/or administer medicines under the patient group direction, is responsible for ensuring that he or she is competent, qualified and trained to do so and for maintaining an up-to-date record of such approved persons in conjunction with the Head of Profession.
The **healthcare professional** who is approved to supply and/or administer medicines under the direction is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration or supply is carried out within the terms of the direction, and according to his or her code of professional practice and conduct.
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Local clinical area(s) where these healthcare professionals will operate this PGD:

Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

Appendix 5

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Individual Authorisation

This PGD does not remove inherent professional obligations or accountability

The **healthcare professional** who is approved to supply medicines under the direction is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. They should submit a copy of their NES Assessment Results Training along with this authorisation form.

The approved person is also responsible for ensuring that the supply is carried out within the terms of the direction, and according to his or her code of professional practice and conduct.

They should also ensure that the organisation that provides their professional indemnity insurance has confirmed that this activity is included in their policy.

Note to Authorising Authority: authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

I have read and understood the Patient Group Direction and agree to provide the varenicline in accordance with this PGD.

Name of Pharmacist _____

GPhC Registration Number _____

Normal Pharmacy Location (if pharmacy locum please provide contact details) _____

Signature _____ Date _____

Signed copy to be returned to Neil Paton, Admin Assistant, Pharmacy Services Office, John Dewar Building, Inverness Retail & Business Park, INVERNESS. IV2 7GE

FAX: 01463 713844