NHS Grampian

Medicines Management Team
Pharmacy and Medicines Directorate
Westholme
Woodend Hospital
Queens Road
Aberdeen
AB15 6LS

Date: 5th of October 2022
Our Ref: FA/PGD/Varenicline/MGPG1059/October22
Enquiries to: MGPG
Extension: 56689
Direct Line: 01224 556689
Email: gram.mgpg@nhs.scot

Dear Colleagues

This letter authorises the extended use of the following Patient Group Direction (PGD) until 1st November 2023:

Patient Group Direction For The Supply Of Varenicline By Authorised Community Pharmacists Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles, Version 1

There are currently supply issues for varenicline that are unlikely to be resolved soon. However, the PGD remains clinically accurate and should stock become available this letter provides permission to continue using the PGD to a new expiry date of 1st November 2023. This letter should be kept with the PGD records and brought to the attention of the individual community pharmacists who operate under the PGD currently.

If you have any queries regarding this please do not hesitate to contact the Pharmacy and Medicines Directorate.

Yours sincerely

Lesley Coyle
Chair of North of Scotland PGD Group

NHS Grampian | NHS Highland | NHS Orkney | NHS Shetland | NHS Tayside | NHS Eileanan Siar Western Isles

Patient Group Direction For The Supply Of Varenicline By Authorised Community Pharmacists Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

Lead Author: Medicines Management Specialist Nurse NHSG	**Consultation Group:** See relevant page in the PGD	**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature: 		**Signature:** 
NoS Identifier: NoS/PGD/VarCP/ MGPG1059	**Review Date:** November 2021 **Expiry Date:** November 2022	**Date Approved:** November 2019

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 1

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	New PGD Adapted from and supersedes NHSG/PGD/varCP/ MGPG829 Version 2, NHSH 04_25_v3, NHST PGD For the Supply of Varenicline (Champix®) By Authorised Community Pharmacists.

Date of change	Summary of Changes	Section heading
September 2019	NoS PGD developed following review of previous NHSG, NHSH and NHST PGDs.	
September 2019	History of Stevens-Johnson Syndrome or Erythema Multiforme added.	Exclusion criteria
September 2019	History of epilepsy or seizures added.	Exclusion Criteria
November 2019	Confidentiality statement changed from GMC advice to that of the GPhC as it's more applicable to the staff group who use the PGD.	General Policy For Community Pharmacist Supplying Varenicline
November 2019	Severe renal impairment added.	Exclusion Criteria
November 2019	Additional advice regarding individuals with mild to moderate renal impairment added.	Precautions and Special warnings
November 2019	Information regarding end of treatment reduction titration pack removed as not applicable.	Dosage/Maximum total dose
November 2019	Information regarding further 12 weeks supply to a total of 24 weeks added.	Maximum or minimum treatment period
November 2019	Statement added in regard to individuals who may require a supply for longer than a week.	Quantity to be supplied
November 2019	Information regarding end of treatment reduction titration pack removed as not applicable.	Appendix 3
November 2019	Appendix 5 with GP Notification Letter removed as this process is now completed across NoS via the electronic Universal Claim Framework.	

NoS Identifier: NoS/PGD/VarCP/MGPG1059
Keyword(s): PGD Patient Group Direction varenicline pharmacist Champix

Policy Statement: It is the responsibility of the individual community pharmacist and their line manager to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document:	Drafted:	September 2019
	Completed:	November 2019
	Approved:	November 2019 (published – November 2019)
	Amended:	

Organisational Authorisations

This PGD is not legally valid until it has had the relevant organisational authorisation.

PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr David Rigby **Health Board:** NHSWI **Title:** GP, Realistic Medicine and Therapeutics Lead **Contact email:** davidrigby@nhs.net **Signature** .....
Senior representative of the professional group who will provide care under the direction	**Name:** Alison Smith **Health Board:** NHSG **Title:** Medicines Management Pharmacist **Contact email:** alisonjane.smith@nhs.net **Signature** .....
Lead author	**Name:** Frances Adamson **Health Board:** NHSG **Title :** Medicines Management Specialist Nurse **Contact email:** f.adamson@nhs.net **Signature** .....
Pharmacist	**Name:** Jackie Agnew **Health Board:** NHSH **Title :** Head of Community Pharmacy Services & CD Governance **Contact email:** Jackie.agnew@nhs.net **Signature** .....

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Thomson		November 2019

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Amanda Croft		November 2019

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

Name:	Title:
Frances Adamson	**Lead Author:** Medicines Management Specialist Nurse NHSG
Jackie Agnew	**Pharmacist:** Head of Community Pharmacy Services & CD Governance NHSH
Dr David Rigby	**Medical Practitioner:** Consultant in Public Health Medicine NHSG
Alison Smith	**Senior Representative:** Medicines Management Pharmacist NHSG
Fiona Leith	Smoking Cessation Advisor NHSG
Stacey Anderson	Pharmaceutical Services Improvement and Development Manager NHSG
Chipego Siamuwele	Public Health Practitioner - Smoking Cessation NHSG
Kirsty Neave	Medicines Management Pharmacist NHSG

General Policy for Community Pharmacist Supplying Varenicline

Supply of Varenicline

Varenicline may be supplied as a core part of the Community Pharmacy National Public Health Service (PHS) contract to support smoking cessation where the pharmacist has completed training relevant to this product, and signed up to the Patient Group Direction (PGD). Payments for the smoking cessation service are made upon timely completion of Pharmaceutical Care Record (PCR) see www.cps.scot for further details. Payments for stock supplied are made upon receipt of electronic Universal Claim Framework (UCF) submissions.

An individual can be considered for either Nicotine Replacement Therapy (NRT) or varenicline, along with support from a community pharmacist following discussion of both options taking cognisance of the individual's preferred choice and their suitability for treatment.

Varenicline must be supplied along with weekly on-going behavioural support which may be provided by staff normally involved in smoking cessation support and the community pharmacist.

The individual must be assessed for varenicline suitability before being signed up to the scheme using the Pharmacist Varenicline Clinical Risk Assessment Form in Appendix 4.

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

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

Authorised Pharmacists

- Varenicline may **only** be supplied by an authorised pharmacist. Pharmacy staff must be trained to refer each request for varenicline to the accredited pharmacist.

- The pharmacist must have successfully completed training approved by NES or as available on TURAS Learn.

Approved Premises

- The service can only be provided in a registered pharmacy, which must have a suitable area for consultation with individuals. This should be a quiet area within the pharmacy with the offer of a private room if 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.

Confidentiality

General Pharmaceutical Council Statement

People trust that their confidentiality and privacy will be maintained by pharmacy professionals, whether in a healthcare setting such as a hospital, primary care or community pharmacy setting, in person, or online. Maintaining confidentiality is a vital part of the relationship between a pharmacy professional and the person seeking care. People may be reluctant to ask for care if they believe their information may not be kept confidential. The principles of confidentiality still apply after a person's death. There are a number of ways to meet this standard and below are examples of the attitudes and behaviours expected.

Individuals receive safe and effective care when pharmacy professionals:

- Understand the importance of managing information responsibly and securely and apply this to their practice
- Reflect on their environment and take steps to maintain the person's privacy and confidentiality
- Do not discuss information that can identify the individual, when the discussions can be overheard or seen by others not involved in their care
- Ensure that everyone in the team understands the need to maintain an individual's privacy and confidentiality
- Work in partnership with the individual when considering whether to share their information, except where this would not be appropriate.

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

Clinical Support

The 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 individual's GP.

Patient Group Direction For The Supply Of Varenicline By Authorised Community Pharmacists Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

Clinical indication to which this PGD applies

Definition of situation/ Condition	This Patient Group Direction (PGD) will authorise community pharmacists to supply varenicline to individuals accessing the PHS smoking cessation service who wish to stop smoking. This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF) and the individual Summary of Product Characteristics (SmPC).
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 • Individuals over 18 years of age • The individual agrees to receive motivational support. Prior to the supply of the medicine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.
Exclusion criteria	• Smokers not sufficiently motivated to quit and those not willing to engage in weekly monitoring and support • Individuals under 18 years of age • Pregnant or breastfeeding women • Sensitivity to varenicline or any of its excipients • Individuals with severe renal impairment and end stage renal disease, e.g. on dialysis • Previous history of Stevens-Johnson Syndrome or Erythema Multiforme • History of epilepsy or seizures • Currently prescribed and using any other smoking cessation therapy, e.g. NRT or e-cigarettes • Community pharmacy patient medication record indicates that the individual is unsuitable for varenicline • Where there is no valid consent.
Precautions and special warnings	**Renal Impairment** Individuals who have mild to moderate renal impairment may be supplied varenicline under this PGD. However, advice should be sought from the individuals GP to ensure the supply is appropriate. No dosage adjustment is necessary for individuals with mild to moderate renal impairment.

	For those individuals with mild to moderate renal impairment who experience adverse reactions that are not tolerable, dosing may be reduced to (500mcg twice daily). **Diabetes** Individuals on insulin may be supplied with varenicline but must be advised to monitor their blood glucose levels closely. **Neuropsychiatric Symptoms** The use of varenicline in individuals with or without a history of psychiatric disorder was not associated with an increased risk of serious neuropsychiatric adverse events. However, clinicians should be aware of the possible emergence of serious neuropsychiatric symptoms in individuals attempting to quit smoking with or without treatment. If serious neuropsychiatric symptoms occur whilst on varenicline treatment, individuals should discontinue varenicline immediately and contact a healthcare professional for re-evaluation of treatment. **Psychiatric Disorders** Individuals with a history of psychiatric illness should be monitored closely while taking varenicline. Individuals should be advised to discontinue treatment and seek prompt medical advice if they develop agitation, depressed mood, or suicidal thoughts. **History of Cardiovascular Disease** Individuals 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. **Interaction with Other Medicinal Products** 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). As smoking induces CYP1A2, smoking cessation may result in an increase of plasma levels of CYP1A2 substrates. Individuals taking medications that may be affected when they stop smoking should be advised to tell their treating physician of their quit attempt.

Action if excluded from treatment	**N.B.** For individuals who continue to smoke beyond the agreed quit date treatment with varenicline must be stopped. Refer to Specialist Smoking Cessation Service for Health Board area or general practitioner. The reason why the individual was excluded under the PGD should be documented in the PMR. **N.B.** Individuals who are excluded from the use of varenicline may be suitable for smoking cessation support using NRT.
Action if treatment is declined	Discuss alternative products if suitable and/or offer referral to the Specialist Smoking Cessation Service for further assessment. The reason why the individual declined treatment under the PGD should be documented in the PMR.

Description of treatment available under the PGD

Name form and strength of medicine	Varenicline 0.5mg and 1mg film-coated tablets.
Legal status	Varenicline is a Prescription-only Medicine (PoM).
Dosage/Maximum total dose	**Individuals should set a quit date to stop smoking and varenicline treatment should usually start 1-2 weeks before this date.** **Days 1 - 3:** 500micrograms once daily **Days 4 – 7:** 500micrograms twice daily **Day 8 to the end of the treatment:** 1mg twice daily (reduce to 500micrograms twice daily if not tolerated) **N.B.** Individuals who cannot tolerate the adverse effects of varenicline may have the dose lowered temporarily or permanently to 500micrograms twice daily. **Maximum single dose 1mg** **Maximum daily dose 2mg**

Frequency of dose/Duration of treatment	For frequency of dose see Dosage/Maximum total dose section above. Individuals should be treated with varenicline for 12 weeks with a 1-week titration at the beginning of the 12-week period.
Maximum or minimum treatment period	Every attempt should be made to reduce the use of varenicline to zero by the end of 12 weeks. This PGD only allows supply for a maximum period of 12 weeks. **N.B.** Individuals may benefit from taking varenicline for an additional 12 weeks to a total of 24 weeks of treatment. However, this decision should be made by the individuals GP and the pharmacist should refer any suitable individuals requesting further supply beyond 12 weeks of varenicline to their GP.
Route/Method of administration	For oral use and the tablets should be swallowed whole with water, can be taken with or without food.
Quantity to be supplied	12 weeks supply of varenicline (Ideally supplied weekly). **N.B.** There may be occasions where two to three weeks supply at a time may be requested. IIn these instances the pharmacist should, where appropriate, supply the necessary number of days supply and arrange a weekly check in where possible e.g. via phone call.
Storage requirements	Store below 30°C.
Follow-up (if applicable)	See Treatment Plan in Appendix 3. Varenicline must be supplied along with weekly support (ideally this should be face to face, but could be via the telephone if this isn't possible).
Advice (Verbal)	Advise individual what to expect and what to do for minor and major reactions. If serious adverse or persistent effects occur, the individual should be advised to contact their GP/Accident and Emergency department/NHS24. **The pharmacist should discuss the major reasons for varenicline failure which are as follows;** • Unrealistic expectations • Lack of preparation for the fact that tablets may cause nausea • Insufficient support.

	It is important to make sure that the client understands the following points: • Varenicline does not guarantee abstinence from smoking, 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 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 • About a third of individuals may experience mild nausea usually about 30 minutes after taking it. This reaction often diminishes gradually over the first few weeks, and most individuals tolerate it without problems. **The following further general advice should also be given:** • Possible changes in the body on stopping smoking e.g. weight gain which can be addressed through diet and exercise • Follow-up and obtaining further supplies • 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 individuals • Individuals taking certain medications that may be affected when they stop smoking should be advised to tell their treating physician of their quit attempt.
Advice (Written)	The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual. Provide Board specific supportive literature (if available) at the pre-quit assessment and encourage the individual to keep a smoking diary prior to returning. Individuals should be encouraged to complete the relevant sections in the NHS Health Scotland Publication 'How to Stop Smoking and Stay Stopped' and bring back to the pharmacy at week one for discussion.
Identifying and managing possible adverse reactions	**Very common (≥ 1/10):** • Nasopharyngitis • Abnormal dreams • Nausea • Insomnia • Headache **Common (≥ 1/100 to < 1/10):** • Bronchitis • Weight increase • Somnolence • Sinusitis • Increased/Decreased appetite • Gastroesophageal reflux disease

	Common Cont. (≥ 1/100 to < 1/10): • Dizziness • Abdominal pain • Cough • Constipation • Dyspnoea • Toothache • Flatulence • Rash • Arthralgia • Back pain • Fatigue • Live function test abnormalities • Abdominal distension • Vomiting • Diarrhoea • Taste disturbance • Dyspepsia • Dry Mouth • Pruritus • Myalgia • Chest pain **This list is not exhaustive. Please also refer to current BNF and manufacturers SmPC for details of all potential adverse reactions.** **BNF**: https://about.medicinescomplete.com/ **SmPC/PIL/Risk Minimisation Material:** https://www.medicines.org.uk/emc/ http://www.mhra.gov.uk/spc-pil/index.htm https://www.medicines.org.uk/emc/rmm-directory If an adverse reaction does occur stop medication immediately and seek advice from a relevant medical practitioner as soon as possible. Report any severe reactions using the Yellow Card System. https://yellowcard.mhra.gov.uk/
Facilities and supplies required	The following are to be available at sites where the medicine is to be supplied/administered: • Appropriate storage facilities • An acceptable level of privacy to respect individual's right to confidentiality and safety • Access to a working telephone • Access to medical support (this may be via the telephone) • A copy of this current PGD in print or electronically.

Characteristics of staff authorised to supply medicine(s) under PGD

Professional qualifications	Pharmacists whose name is currently on the register held by the General Pharmaceutical Council (GPhC).

Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual's capacity to understand the nature and purpose of the medicine supply in order to give or refuse consent • Aware of current treatment recommendations and be competent to discuss issues about the medicine with the individual • Having undertaken and passed the NES Scottish Community Pharmacy Smoking Cessation Programme and/or the equivalent TURAS Learn modules • Competent to undertake the supply of the medicine • Competent to work under this PGD.
Ongoing training and competency	**All professionals working under this PGD must:** • Have undertaken PGD training as required/set out by each individual Health Board • Maintain their skills, knowledge and their own professional level of competence in this area according to their Standards for pharmacy professionals • Have knowledge and familiarity of the following; o SmPC for the medicine(s) to be supplied in accordance with this PGD.
Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above. Maintain up to date record of all staff authorised to supply the medicine(s) specified in this direction.

Documentation

Authorisation of supply	Community pharmacists working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to supply the medicine(s) specified in this PGD when they have completed local Board requirements for service registration and/or by their Director of Pharmacy. All authorised staff are required to read the PGD and sign the Agreement to Supply Medicines Under PGD (Appendix 1). A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.

Record of supply	An electronic or paper record for recording the screening of individuals and the subsequent supply of the medicine(s) specified in this PGD must be completed in order to allow audit of practice. The PCR must be used for recording the Minimum Data Set (MDS) of information prior to the supply of varenicline. This should include: • Individuals' 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 individual. • Details of any adverse drug reaction and actions take. • Advise GP that individual has commenced treatment with varenicline.
Audit	All records of the medicine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.
References	Electronic Medicines Compendium http://www.medicines.org.uk. Champix®. Date of revision of text July 2019, accessed 11/09/19. British National Formulary https://about.medicinescomplete.com/ accessed 11/09/19. NICE Smoking cessation (2007) – Varenicline: http://guidance.nice.org.uk/TA123 General Pharmaceutical Council - In practice: Guidance on confidentiality (2017). https://www.pharmacyregulation.org/sites/default/files/in_practice-_guidance_on_confidentiality_may_2017.pdf

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 1

Healthcare Professional Agreement to Supply Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to supply the medicine(s) contained within the following Patient Group Direction:

Patient Group Direction For The Supply Of Varenicline By Authorised Community Pharmacists Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

I have completed the appropriate training to my professional standards enabling me to supply the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 2

Healthcare Professionals Authorisation to Supply Medicine(s) Under Patient Group Direction

The Lead manager/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 Senior Nurse/Professional who approves a healthcare professional to supply the medicine(s) under this PGD 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.
The Healthcare Professional that is approved to supply the medicine(s) under this PGD 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 supply is carried out within the terms of the direction, and according to his or her individual code of professional practice and conduct.
Patient Group Direction For The Supply Of Varenicline By Authorised Community Pharmacists Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

Patient Group Direction For The Supply Of Varenicline By Authorised Community Pharmacists Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**

Appendix 3 - Treatment Plan

Consultations	Treatment plan
Pre-quit attempt (Assessment)	Complete the Pharmacist Varenicline Clinical Risk Assessment Form (Appendix 4) and if the individual is suitable for varenicline supply, complete the MDS via the PCR. Discuss setting a formal quit date and the need to start varenicline around 1-2 weeks before this date. You can set the quit date in the PCR at this stage. Arrange an appointment for the individual 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 individual to keep a smoking diary prior to returning at Week1.
1st week	Ensure the individual has set a quit date. Monitor carbon monoxide level. Supply 14 day starter pack (11 x 500micrograms tabs with 14 X 1mg tablets). *Make arrangement to see individual again before tablets run out, i.e. between days 7 - 14. Update PCR with details
3rd week visit	If they are still smoking, he/she should be informed that treatment with varenicline would have to be stopped if they continue to smoke. Monitor carbon monoxide level. Supply 1mg varenicline tablets if required. Make arrangement to see the individual the following week. Update PCR with details.
4th - 12th week visits	Monitor carbon monoxide level and check if the individual has stopped smoking. **If they are still smoking, treatment with varenicline should be stopped.** If the individual has quit smoking supply 1mg varenicline tablets as required. If side effects are tolerable then continue supplying varenicline 1mg tablets as required. If an individual is troubled by side effects assess whether they are tolerable or whether supply should be stopped. During or after this time the PCR should be updated in a timely manner in regard to the medication supplied and any advice given. This should be done as soon as possible after each consultation with the individual.

Appendix 4 - Pharmacist Varenicline Clinical Risk Assessment Form

Pharmacy Stamp or Details	Individual's name: Address: Telephone number: Date of birth: GPs name and address:

Factor	Yes	No	Notes
Is the individual under 18 years of age			If ' yes' - refer
Is the individual pregnant or breastfeeding?			If ' yes' - refer
Does the individual suffer from severe renal impairment or have end stage renal disease?			If ' yes' - refer
Does the individual suffer from epilepsy or have a history of seizures?			If ' yes' - refer
Is the individual currently using another smoking cessation therapy?			If ' yes' – refer or discuss switching to varenicline if appropriate
Is the individual on any other medications?			Please list. Check SmPC for interaction
Is the individual sensitive to varenicline or any of its excipients?			If ' yes' - refer

Special circumstances and any other relevant notes:

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. **Individual'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: