



Dear Colleague

PUBLIC HEALTH SERVICES (PHS) - SMOKING CESSATION SERVICE REVISED SERVICE SPECIFICATION

Summary

1. This Circular advises of changes to the Smoking Cessation Service available through Community Pharmacy and includes the revised Service Specification and varenicline PGD.

Background

2. A Review of Public Health Services was undertaken in 2010, part of which reviewed the early progress of the smoking cessation service using nicotine replacement therapy (NRT), provided under the Public Health Service element of the Community Pharmacy Contract.

3. The review showed that smoking cessation services have in the main been positively received providing easy access to NRT for those wishing to quit and valuable support during the process.

4. However a number of recommendations were made as to how the service could be improved with respect to increasing quit rates such as enhancing quit rates by more robust follow up arrangements with users and increasing the range of products available.

5. Following consideration of the recommendations, the Smoking Cessation Service Specification has been updated to include new reporting and payment arrangements and also inclusion of the provision of varenicline (Champix) as a treatment option.

16 June 2014

Addresses

For action

Chief Executives, NHS Boards

For information

Chief Executive
NHS NSS
Director of Practitioner Services,
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Detail

6. A copy of the revised Smoking Cessation Service Specification is attached at **Annex A**

7. A copy of the varenicline Patient Group Direction (PGD) is attached at **Annex B**. The Service Specification includes;

- **Appendix 1** - Treatment Plan
- **Appendix 2** - Client Assessment Proforma & Record Sheet
- **Appendix 3** – Supply of Product Letter to GP

8. Further information and a copy of all documents are available at http://www.communitypharmacy.scot.nhs.uk/core_services/phs.html

9. The content of this circular has been agreed with Community Pharmacy Scotland.

Pharmacist Training and Resource Pack

10. A training pack is being made available to all community pharmacy contractors and their support staff to help implement the service. The pack can be accessed at <https://www.portal.scot.nhs.uk>

NHS Board Requirements

11. NHS Boards are responsible for:

- defining the criteria for localised varenicline PGD
- the signing and clinical governance of the varenicline PGD; and
- providing a contact point for advice and help with regard to completing MDS data and this includes:
 - undertaking visits to offer support,
 - providing training, support materials and updates on service changes,
 - providing feedback to pharmacies on performance; and addressing quality assurance issues which may arise; and
 - best practice guidance in relation to helping pharmacies carry out patient follow-up at 4 & 12 weeks

Action

12. NHS Boards are asked to note the above NHS Board requirements and to copy this circular to all community pharmacy contractors on their list

Yours sincerely

Bill Scott

Chief Pharmaceutical Officer and Deputy Director, Pharmacy & Medicines Division

PHARMACEUTICAL SERVICES SPECIFICATION

PROVISION OF A SMOKING CESSATION SUPPORT SERVICE

1. Service aim

- 1.1 The community pharmacy smoking cessation support service is part of the Public Health Service (PHS) element of the community pharmacy contract. It aims to provide extended access through the NHS to smoking cessation support, including the provision of patient centred behavioural support and evidence-based pharmacotherapies, in line with the national service standards (see section 3). Patients are supported in their attempts to quit smoking and to sustain and improve their health while working towards a healthier lifestyle. **The specific service procedures for Nicotine Replacement Therapy (NRT) and varenicline are laid out in the enclosed Appendices A and B.**
- 1.2 This service specification includes **best practice guidance** and must be read in conjunction with any local guidance and/or protocols. Local procedures should be followed where required.

2. Service outline

2.1 General

- 2.1.1 The community pharmacy smoking cessation service should be person-centered, patient-friendly, non-judgemental and confidential.
- 2.1.2 The service must be delivered from premises that can provide an acceptable level of confidentiality such as a consultation room (or counselling area away from earshot of other patients and customers if not available).
- 2.1.3 The service is available to any patient aged 12 years or over. Consent of a parent or legal guardian is required if the patient is under 13 years of age. Pharmacists should follow the advice of the Caldicott Guardian in their local health board on establishing and recording consent for patients without capacity. The patient must also be registered with a GP practice in Scotland.
- 2.1.4 The smoking cessation support service, as part of the Public Health Service contract should be available throughout standard opening hours of the pharmacy to all patients requiring assessment and support. Pharmacies that experience difficulties in providing sufficient capacity to enable this must inform Primary Care Services at their local health board
- 2.1.5 It is important that all pharmacists and members of pharmacy support staff who help to deliver the pharmacy smoking cessation service are trained to nationally recognised in-depth/intensive smoking cessation standards as described in section 4.

- 2.1.6 Publicity materials and patient information made available by Scottish Government through the PHS can be used to advertise the service in the pharmacy. NHS boards may also choose to make these and their own materials available in other relevant settings (for example local GP practices and health centres, community centres etc.). NHS Health Scotland has a range of free support materials including publications and Smokeline cards which are available from your local NHS health information resource library/centre or by directly contacting NHS Health Scotland.
- 2.1.7 Information about service activity and outcomes is recorded through the smoking cessation support tool available within the Pharmacy Care Record (PCR). It forms part of the national data that are collected by smoking cessation services for each patient undertaking a quit attempt. Minimum Data Set (MDS) data are electronically submitted from PCR to the national smoking cessation database. The national smoking cessation database is made available to the local NHS board for assessment and monitoring purposes. Pharmacy contractors are paid on the electronic submission of a completed MDS form within the specified time frames.

2.2 Contractors, pharmacists, pharmacy support staff

- 2.2.1 The pharmacist and support staff should proactively seek patients for the service within the pharmacy. Examples of suitable patients include those with cardiac or respiratory disease, pregnant women, young people and lower socio-economic groups. These patients may also have individual support needs, requiring consideration of the procedures described at paragraph 2.2.9 regarding referral to specialist smoking cessation support services.
- 2.2.2 The patient's details are recorded in the smoking cessation support tool within PCR. The patient's motivation to quit should also be explored at this stage and an appropriate provisional quit date agreed. The patient should be offered a **return appointment** prior to or on the provisionally agreed quit date. The timing of this should be flexible (e.g. several days or a week later or longer). The purpose of this is to ensure only genuinely motivated patients return and this therefore increases the likelihood of success. It also enables sufficient planning and preparation for the quit attempt. However, assessing readiness to quit is subject to professional judgement and it is possible that some smokers requesting smoking cessation support services may be sufficiently prepared with their own planning to be able to commence their quit attempt on their first visit.¹
- 2.2.3 At the return appointment the patient should be seen by either the pharmacist or another member of pharmacy support staff who has been trained to nationally recognised smoking cessation standards as described in section 4. The training records of staff who offer the smoking cessation service should be available for inspection by NHS Board staff.

¹ Local guidance should be followed in assessing readiness to quit

- 2.2.4 The pharmacist or trained pharmacy support staff then assesses the patient and records within PCR all additional patient data required to complete the MDS data including a confirmed quit date and selection of pharmacotherapy. This date along with the initial data captured will be electronically submitted to the national smoking cessation database and will be used to form the basis of the timescales for the quit attempt, 4-week and 12-week post-quit date follow-ups as well as activating the first remuneration payment for the service.
- 2.2.5 Having completed the initial assessment the pharmacist, or trained support staff supplies the appropriate pharmacotherapy in consultation with the patient. This should be in line with national guidance² and in accordance with the process detailed in the appropriate service procedure at **Appendix A or B. Varenicline should only be supplied by the pharmacist.** It should also comply with local prescribing guidance, formularies and/or protocols. Consideration should be given to the selection of the product(s) and appropriate quantity for the prescribing instalments. The supply should be recorded on a CPUS form for reimbursement purposes. The patient should expect on-going support and further supplies of pharmacotherapies for up to a 12-week time period. The supply may be extended over the 12-week period and recorded on PCR according to local NHS Board guidelines. However, whilst the pharmacotherapy costs will be reimbursed, no further payment can be claimed for the support element of the supply beyond the 12-week point. Pharmacists should use their professional judgement on how long to continue providing a patient with NRT by considering individual circumstances. If a patient is assessed as requiring continued support after the 12 week period has been completed, then referral to the health board, through a locally agreed protocol, should be considered.
- 2.2.6 Where NRT is provided the follow-up visit consultations can be undertaken by a trained member of pharmacy support staff. **It is preferable for continuity of service that (with the exception of the initial supply), the same member of staff provides the on-going support to the patient.** Any adverse issues arising around the choice of pharmacotherapy which are identified by a trained member of pharmacy support staff should be discussed with the pharmacist. The CPUS prescription must always be signed by the pharmacist and patient in the appropriate areas.
- 2.2.7 Where varenicline is provided under the national Patient Group Direction (PGD) the follow-up consultations must be undertaken by a **pharmacist** in accordance with the procedure described in **Appendix B** and any additional local guidance. The GP should be informed using the standard letter (as detailed in the NES pack, <https://www.portal.scot.nhs.uk>). The GP letter template is available at http://www.communitypharmacy.scot.nhs.uk/core_services/phs.html
- 2.2.8 Any suspected side effects or adverse reactions, in particular associated with varenicline, must be reported through the Medicines and Healthcare products Regulatory Agency (MHRA) Yellow Card Scheme. <http://yellowcard.mhra.gov.uk/>.

² NHS Health Scotland and ASH Scotland (2010). *A Guide to smoking cessation in Scotland 2010*. NHS Health Scotland, Edinburgh. <http://www.healthscotland.com/documents/4661.aspx>

2.2.9 The community pharmacy smoking cessation service is an integral part of NHS Boards' wider smoking cessation services. Signposting and cross-referrals between the different smoking cessation service providers, such as community pharmacies, specialist smoking cessation services, GPs and other health professionals in primary and secondary care must be actively undertaken.

Patients who should be referred to NHS Board specialist smoking cessation services include those who:

- have had two or more previous unsuccessful quit attempts
- may require more intensive input
- may benefit from group sessions
- are particularly struggling with cravings or stress.

2.2.10 Carbon monoxide (CO) validation of a smoker's quit attempt is an encouraging and motivational tool as well as aiding discussion on smoking issues. **CO validation should be offered at each appointment.** CO monitoring is a requirement at the 4 weeks and 12 weeks post quit follow up appointments where the reading should be recorded on the PCR. CO monitors should be made available by NHS Boards, and used and maintained/calibrated in line with manufacturers' instructions.³

2.2.11 The pharmacist is responsible for keeping and maintaining records for each supply/intervention. They are also responsible for ensuring that they, or a designated member of support staff, complete the smoking cessation support tool within PCR and submit it electronically in accordance with the timescales and process laid out at Section 5.2. The contractor/pharmacist may be required to share information with appropriate parties, such as their NHS Board or National Services Scotland (NSS) personnel in accordance with confidentiality protocols. In line with Data Protection requirements, patients should be made aware that their data will be recorded on the national database and that they will be contacted for follow-up at a later date, and if they don't attend for a follow up appointment. The patient must consent to follow up in order to participate in the service.

2.2.12 Patient follow up at 4-weeks and 12-weeks post-quit date, as detailed at section 5.2.5, should be undertaken in the pharmacy and a CO breath test carried out, in a consultation room or other suitable area. Only patients smoke-free at 4 week post quit date should be followed up at 12 weeks post quit date. The results must be recorded in the smoking cessation support tool within PCR. **Payment for the support element of the service is linked to completion and electronic submission of MDS data within PCR as described in section 5.2.6.** It is imperative that patient follow up is carried out using the timescales and process laid out at **sections 5.2.3 - 5.2.6** and further in Appendices A and B and that data are electronically submitted to enable payment claims to be assessed and payments processed. **Pharmacy contractors should be aware that payments may be withheld where data discrepancies occur or MDS data have not been submitted in a timely manner.**

³ Local guidance should be followed regarding provision, maintenance and use of CO monitors

2.2.13 The pharmacist must ensure that, as set out in the Public Health Service Specification, patients are provided with a range of appropriate healthy living advice including exercise and diet and referred or signposted to other support services as appropriate. Written information should also be available to support this.

2.3 NHS Boards

2.3.1 CO monitors and accessories should be made available by NHS Boards, and used and maintained/calibrated in line with manufacturer's instructions.⁴

2.3.2 NHS Boards will assess payment claims versus data collection and process payments.

2.3.3 NHS Boards may extend the period of support provided by community pharmacies according to local NHS Board guidelines in line with section 2.2.5. Any such arrangement will cover pharmacotherapy reimbursement costs but not additional remuneration for the service through the PHS service specification.

2.3.4 **NHS Boards should provide access to a 'how to' set of materials which include prescribing protocols, sample resources, referral pathways and details of any training opportunities. These materials will complement boards' service quality assurance systems.**

2.3.5 **NHS Boards have a clinical governance responsibility for the signing of the localised Patient Group Direction (PGD.)**

3. Service Standards and Quality Assurance

3.1 General

3.1.1 The service should comply with any policies and standards set by the NHS for the provision of such services regardless of setting. **Up to date national guidance is available within [A guide to smoking cessation in Scotland \(2010\)](#)⁵ and revised definition of smoking cessation services (2012) published by NHS Health Scotland.**

3.1.2 The service should be provided according to standards set by the General Pharmaceutical Council (GPhC) or Royal Pharmaceutical Society of Great Britain (RPSGB).

3.2 Contractors, pharmacists, pharmacy support staff

3.2.1 Pharmacy contractors must ensure that the pharmacist and any trained pharmacy support staff providing the service are aware of and operates within the National Service Specification.

⁴ Local guidance must be followed regarding provision, maintenance and use of CO monitors

⁵ NHS Health Scotland and ASH Scotland (2010). *A Guide to smoking cessation in Scotland 2010*. NHS Health Scotland, Edinburgh. <http://www.healthscotland.com/documents/4661.aspx>

3.2.2 Pharmacists and pharmacy support staff will be expected to deliver the service to the standards detailed in the table below:

Service standards

- All pharmacists and members of pharmacy support staff should be trained using nationally recognised training - NES Smoking Cessation Mandatory Training Materials 2014 (direct events or webinar or e-learning package)
- All patients will have a quit-date set and submitted electronically to Practitioners Services Division (PSD) to enable full completion of the national minimum data set.
- All patients will be offered the most appropriate form of pharmacotherapy for their assessed needs, i.e. NRT (including the option of combination NRT) or varenicline. Where a patient is provided with varenicline to support their stop smoking attempt, the GP should be informed using the standard letter in the NES pack, <https://www.portal.scot.nhs.uk>. The template can be found at http://www.communitypharmacy.scot.nhs.uk/core_services/phs.html
- Pharmacotherapy will be provided in conjunction with the setting of a quit date, on an abstinence-contingent basis, in line with *A Guide to Smoking Cessation in Scotland 2010's* Planning and Providing Specialist Smoking Cessation Services component (pp 21–23), and supplied in accordance with local prescribing guidance, formularies and/or protocols.
- Any suspected adverse events will be reported using the MHRA Yellow Card Scheme
- All patients should be offered weekly behavioural support and CO validation at each appointment (ordinarily on a one to one basis) normally over a 12-week period.
- All patients must be followed up 4-weeks post-quit date and of those recorded as non-smokers, 12-weeks post-quit date and outcome recorded in the MDS PCR smoking cessation support tool and electronically submitted to PSD to enable full completion of the national minimum data set.

3.2.3 NHS Boards will quality assure community pharmacy performance by monitoring data completion and timely submission of MDS data, data completion versus reimbursement / remuneration claims and quit rates. **Pharmacy contractors should be aware that payments may be withheld where discrepancies occur or MDS data are not submitted.**

- 3.2.4 **The community pharmacy contractor should ensure that a standard operating procedure is in place which covers all aspects of the community pharmacy service provision and guides staff on their required actions for each stage of a patient's quit attempt.**

3.3 NHS Boards

- 3.3.1 NHS Boards will quality assure community pharmacy performance as laid out in section 3.2.2, Service Standards.
- 3.3.2 NHS Boards should assist improvements in service delivery by providing support and feedback to community pharmacies on performance against any national and/or local quality indicators and/or expected levels of performance, which may include, where relevant, the comparison of performance against other community pharmacies.
- 3.3.3. NHS Board personnel should engage with community pharmacists on a regular basis to promote partnership working with NHS Smoking Cessation Service providers and to ensure that an effective, high quality overall local smoking cessation service is provided. Mentoring should be provided to those pharmacies that do not achieve the activity levels required by their local community, have poor quit rates or regularly return poor quality, missing or incomplete data.
- 3.3.4 To contribute to ongoing continuing professional development, NHS Boards should also enable access to regular update/refresher training opportunities and/or toolkits and share best practice at NHS board and community pharmacy level.

4. Training

4.1 General

- 4.1.1 Nationally recognised direct learning events, webinar/webcast or an e-learning resource package is available from National Education for Scotland (NES) for pharmacists and pharmacy support staff who wish to develop their knowledge and skills in the area of smoking cessation. The training must be satisfactorily completed as per NES performance indicators by completing the appropriate assessments to a satisfactory standard, to be able to deliver smoking cessation services.
- 4.1.2 NHS Boards can deliver their own training, however one aspect of this must be based on the NES pack (<https://www.portal.scot.nhs.uk>) and the assessment while the other can focus on locally agreed service provision. NHS Boards will issue Completion Certificates for amended training to successful delegates if not issued by NES.

NHS Health Scotland has a Virtual Learning Environment (VLE) which provides a Health Behaviour Change e-learning suite.

All the modules can be accessed using this URL link;

<http://elearning.healthscotland.com/course/index.php?categoryid=108>

4.1.3 The pharmacy owner or superintendent pharmacist of the pharmacy is responsible for ensuring that all pharmacists and support staff providing this service can provide a completion certificate for the training relevant to their role and/or other clear evidence that they are competent to offer this service.

4.2 Contractors, pharmacists, pharmacy support staff

4.2.1 The pharmacist and any member of pharmacy support staff providing the service should practise within their own competency and should attend suitable revision/update training sessions to ensure continued personal and professional development and competency.

4.2.2 Prior to service delivery, nationally recognised training must be undertaken by pharmacists and any members of pharmacy support staff who provide the service. Staff should be competent to:

- Prepare the patient for stopping, advise on the health benefits of stopping,
- Provide practical information and advice such as advice on expected weight gain, addressing cravings and routine changes which may need to be adopted,
- Be able to discuss a follow-up support plan,
- Be able to address issues of a patient wishing to re-enter the service after a failed quit attempt and assessing motivation levels,
- Provide advice on high CO readings when patient self-reports as having quit,
- Provide support materials,
- Advise on locally-available services and potential for cross-referrals.

4.3 NHS Boards

4.3.1 NHS Board should provide local smoking cessation training either delivered by the Board or by a centrally appointed external provider.

4.3.2 NHS Boards should ensure that details of and access to any approved NHS Board training are made available as appropriate.

5. Record keeping

5.1 General

5.1.1 It is a requirement of the service that appropriate records are kept and maintained, for three years, to enable verification of service provision and training undertaken.

5.1.2 **The full, accurate and timely completion and submission of the community pharmacy MDS data are key to NHS Boards meeting their HEAT target on the number of successful quits and also provides Boards with an important overall record of each quit attempt.**

5.2 Contractors, pharmacists, pharmacy support staff

5.2.1 Pharmacy contractors must provide information, for internal and external audit and evaluation purposes including to the NHS Board for subsequent Payment Verification checks and Information Services Division (ISD) statistical and monitoring purposes.

5.2.2 For **every patient and every new quit attempt** (i.e. for every patient for whom payment is claimed) the pharmacist or a member of pharmacy support staff is required to collect the agreed smoking cessation minimum dataset (MDS).

5.2.3 The pharmacist or member of pharmacy support staff must collect consistent, accurate and complete patient information, in line with the smoking cessation MDS guidelines and data definitions. **MDS data must be recorded and electronically submitted in accordance with the timescales described in section 5.2.6 to ensure it available for incorporation in the national monitoring statistics.** The pharmacy data are an **essential** part of national monitoring procedures and no remuneration payment for the service will be made until all required data are recorded within PCR and electronically submitted from PCR.

5.2.4 The smoking cessation minimum dataset monitoring requires patient follow-up at 4-weeks, 12-weeks and 12-months post-quit date. The pharmacist or designated member of pharmacy support staff **is responsible for undertaking the 4-week and 12-week post-quit date follow-up and recording the data in the smoking cessation support tool within PCR.**

5.2.5 **The smoking cessation support tool within PCR will not allow a submission out with the allowable time periods.** Follow up at **4-weeks must** be completed and **submitted electronically** between the 4 and 6 week point (measured from the quit date). Follow up at **12-weeks must** be completed and **submitted electronically between the 12 and 14 week point** (again measured from the quit date). **The national smoking cessation database cannot accept data on follow up completed outside these timescales; every effort must be made to contact the patient during these periods, otherwise patients will be considered lost to follow up.** If at any point the patient is no longer attending the pharmacy and is not contactable, it should be recorded in the MDS data in PCR and submitted electronically by PCR. (If the patients quit attempt is known to have failed during the period the PCR may be submitted between 10 and 14 weeks.) Further information on the MDS procedure is available at [Guidelines for using MDS](#). The 12-month post quit date follow-up will be carried out centrally.

5.2.6 The timescales and payment schedule for submission of MDS data are laid out below:

Quit attempt event	MDS submission	Remuneration basis
Submission of the MDS information with confirmed quit date (normally first return appointment)	To be electronically submitted once the quit-date is confirmed with client. This will form the basis of the timelines for the 4-week and 12-week post-quit date follow-ups.	At the end of each calendar month a count will be made, by Practitioner Services Division (PSD), on the central smoking cessation database of patients for MDS submissions for new quit attempts that meet the validation requirements that have not been remunerated
Four week post-quit date	To be electronically submitted immediately after the 4-week post- quit date and not later than 6 weeks from the confirmed quit-date.	At the end of each calendar month a count will be made, by Practitioner Services Division (PSD), on the central smoking cessation database of patients for MDS submissions for the 4-week stage that meet the validation requirements that have not been remunerated
Twelve week post-quit date	To be electronically submitted between 12 and 14 weeks from the confirmed quit-date. (If the patients quit attempt is known to have failed during the period the PCR may be submitted between 10 and 14 weeks.)	At the end of each calendar month a count will be made, by Practitioner Services Division (PSD), on the central smoking cessation database of patients for MDS submissions for the 12-week stage that meet the validation requirements that have not been remunerated

The Pharmacist must attempt to **contact the patient on 3 separate occasions** at week 12.

5.3 NHS Boards

5.3.1 NHS Boards are responsible for

- updating the local Boards providing a contact point for advice and help with regard to completing MDS data:
- undertaking visits to offer support,
- providing training, support materials and updates on service changes,
- providing feedback to pharmacies on performance; and addressing quality assurance issues which may arise; and
- best practice guidance in relation to helping pharmacies carry out patient follow-up at 4 & 12 weeks

5.3.2 NHS Boards are required to attempt to follow up patients unable to be contacted at week 12. Attempts should be made to follow up with the patient between 14 and 16 weeks

5.3.3 NHS Boards must notify pharmacists of the steps to be taken if patient is lost to follow up after they have attempted to contact them on 3 occasions.

Appendix A - NRT Service Procedure

Pre-quit attempt: when the patient is initially identified the pharmacist or trained member of pharmacy support staff follows the procedure detailed below:

- Assess the patient's current smoking status and previous quit attempts (if any). Obtain consent to follow-up the patient, in accordance with local board Caldicott Guardian advice. Record contact details for the patient including telephone numbers.
- Check if the patient is motivated to stop smoking.
- Ascertain if other options are preferable e.g. group sessions – if so refer to specialist smoking cessation services.
- Discuss the advantages and disadvantages of stopping smoking.
- Stress that this is a “Stop Smoking” programme, not a reducing programme.
- Provide written information on the NRT options for the patient to consider.
- Explain the patient pathway and his/her commitment to attend sessions.
- Record the patient's details and motivation to quit in the smoking cessation support tool within PCR. Discuss setting a formal quit date around 7 days after initial visit if the patient is deemed ready to quit. Do not set the quit date in the smoking cessation support tool at this stage
- Arrange an appointment at a mutually convenient time for the patient to return for NRT and further support, as near as possible to the quit date.
- Provide supportive literature and encourage the patient to keep a smoking diary prior to returning. The patient should be encouraged to complete relevant sections of the NHS Health Scotland publication 'How to Stop Smoking and Stay Stopped' and bring back to the pharmacy at week 1 for discussion.

DO NOT routinely provide NRT at this visit

Return appointment - Quit Date: when the patient attends the return appointment the pharmacist or trained member of pharmacy support staff follows the procedure detailed below for the return appointment:

- Determine the patient's initial smoking status using a Carbon Monoxide (CO) monitor.
- Discuss pages from the relevant sections of the 'How to Stop Smoking and Stay Stopped' booklet to ensure the patient wants to stop smoking.
- Assess the patient in order to select the appropriate choice of NRT and identify the supply interval (e.g. at weekly intervals) in accordance with local and national guidance¹ and local prescribing protocols. Ensure patient has been fully assessed for the use of NRT in relation to medical conditions, medicines, and pregnancy/breastfeeding. Ensure that the patient is provided with the appropriate strength of NRT product to enable them to manage their nicotine withdrawal effectively. Consider supply of an NRT product additional to the patch e.g. gum or spray, to help them manage cravings.
- Confirm the quit date for within the next few days.
- Complete a CPUS form for each supply of NRT made. Ensure that the **patient's CHI number is recorded on the form for payment**

- Record any additional patient data in the smoking cessation support tool within PCR.
- Record the results of the CO reading in the smoking cessation support tool within PCR.
- Electronically submit the MDS data detailing the quit date from PCR immediately after the appointment.
- Provide the initial supply of NRT to the patient as per the identified supply interval.
- Provide advice (both written and verbal) to the patient taking into account national and local guidance.
- All advice and support offered should be in line with evidence based practice as outlined in the National Smoking Guidelines (Scotland)
- Identify triggers for smoking (utilise smoking diary) and suggest changes or avoidance strategies for familiar routines.
- Provide tips to help a quit attempt e.g. :-
 - Remove any temptations
 - Get buy-in for quit attempt from family & friends
 - Prepare for the quit day
 - Keep hands busy
 - **BE POSITIVE!**
 - Throw out smoking items
 - Drink plenty of water and eat fruit and vegetables
 - Encourage exercise
 - Reward themselves if they remain quit
 - Provide Smokeline contact details and encourage the patient to use the service for additional support.
- Explain to the patient the use of the recording of their data on the national database, i.e. that by signing the CPUS form they are consenting for data sharing with relevant NHS personnel and that they may be contacted for follow-up at a later date.
- Invite the patient to attend the pharmacy to receive ongoing support and further supplies of NRT for up to a 12-week time period. This may be extended where local NHS Board guidelines allow. The supply should normally be on a weekly basis particularly during the first 4 weeks. This can be extended to suit the patient's needs in later weeks but should not exceed 4 week's supply.
- The 4-week post-quit date session should always be conducted at the appropriate time.
- Explain to the patient that if they do not attend any arranged appointments they will be contacted to reschedule.
- The smoking cessation support tool within PCR will check for other quit attempts (with quit date confirmed) at other community pharmacies. If another quit attempt has been recorded within the last 12 weeks, irrespective of the status of the quit attempt, a new quit attempt cannot be started. The patient can only undertake a new quit attempt within 12 weeks if doing so at the same pharmacy as the previous quit attempt.

Subsequent weeks prior to 4-week post-quit date follow-up appointment: the pharmacist or trained member of pharmacy support staff follows the procedure detailed below.

- Ask how the patient “got on” during the past week
- Determine the patient’s smoking status at each supply interval using the CO monitor to provide feedback.
- Record the results of the CO reading in the smoking cessation support tool within PCR.
- Assess compliance with and suitability of product. Reinforce the correct use of NRT – check strength and formulation are still appropriate
- Discuss what has gone well and what has gone less well, coping strategies, support from family, withdrawal symptoms.
- Give practical advice and help in dealing with problems related to the quit attempt.
- Advise on diet e.g. avoid sugary snacks between meals, try fruit or vegetables instead.
- Give encouragement to continue in the quit attempt
- Make subsequent supplies against each defined supply interval. It is preferable for continuity of service that the same member of staff provides the ongoing support to the patient.
- Arrange follow up appointments. Follow-up patients who do not present as anticipated e.g. through a proactive telephone call or text message. At least **three** attempts should be made to follow-up with patients who have not presented according to local NHS Board procedures. Dates and times of attempts to contact should be recorded within the smoking cessation support tool. If no response after two missed visits and three attempts of contact then inform the Board through a locally agreed protocol.
- If the patient is deemed to have ended their quit attempt, then this should be recorded within PCR and the MDS submitted electronically in the time period defined in section 5.2.6.

Four-week post quit-date follow-up appointment: the pharmacist or trained member of pharmacy support staff follows the procedure detailed below:

- Determine the patient’s smoking status using the CO monitor to provide feedback.
- Record the results of the CO reading in the smoking cessation support tool within PCR
- Electronically submit the MDS data from PCR **immediately** after the four-week post-quit date appointment or in accordance with local Board protocols but no later than six-week post-quit date.
- Patients who do not attend the arranged appointment should be contacted to reschedule. If no response after three attempts of contact then record in the MDS within PCR and submit it electronically.

If at the 4-week post-quit date follow-up the patient reports having smoked in the last two weeks then the pharmacist or trained member of pharmacy support staff should follow local NHS Board procedures. Where there is no local guidance the pharmacist or trained member of pharmacy support staff should deem the quit attempt to have ended and record as unsuccessful in which case further supplies of NRT should be ceased and any further cessation support to the patient should be defined as a new quit attempt. In this circumstance once the

4 week submission has been made the quit attempt should be completed in the smoking cessation support tool.

Under these circumstances a **new quit attempt** can be started at any point thereafter based on the professional judgement of the pharmacist as long as the **new quit attempt is undertaken at the same community pharmacy**. It should be noted however that evidence indicates it is best to allow time to elapse for patients to renew motivation, re-prepare, and have a better chance at a subsequent quit attempt. Local guidance must be followed regarding the timing of a new quit attempt.

The pharmacist should also determine at this stage whether the patient may have a higher chance of success in any new quit attempt within an alternative more intensive smoking cessation support setting and where appropriate, consider referral to other NHS Board Specialist Smoking Cessation Services according to an individual's needs.

Any new quit attempt must be recorded as a new smoking cessation support tool entry in PCR recording as complete the previous attempt.

Subsequent weeks prior to the 12-week post-quit date follow-up appointment: After the 4-week post-quit date attempt follow-up appointment the pharmacist or trained member of pharmacy support staff follows the procedure detailed below:

- Ask how the patient "got on" during the past week and assess compliance with and ongoing suitability of product
- Determine the patient's smoking status at each supply interval using the CO monitor to provide feedback according to local guidance
- Record the results of the CO reading in the smoking cessation support tool within PCR.
- Make subsequent supplies at each defined supply interval. It is preferable for continuity of service that the same member of staff provides the on-going support to the patient.
- At weeks 5 and 9 (or where appropriate to the product guidance) re-assess the patient in order to select the appropriate strength of NRT and supply interval in accordance with national guidelines⁶ and local prescribing protocols with the aim of discontinuing by the end of the 12-week period.
- Complete a CPUS form for the appropriate supply quantities of NRT. Do not endorse with a total quantity to be dispensed weekly.
- Discuss what has gone well and what has gone less well, coping strategies, support from family, withdrawal symptoms.
- Continue to give encouragement and advice (both written and verbal) as required by the patient and according to national and local guidance in order to support the quit attempt
- Arrange follow up appointments
- Follow-up patients who do not present as anticipated e.g. through a proactive telephone call or text message. As before, at least **three**

⁶ NHS Health Scotland and ASH Scotland (2010). *A Guide to smoking cessation in Scotland 2010*. NHS Health Scotland, Edinburgh.
<http://www.healthscotland.com/documents/4661.aspx>

attempts should be made to follow-up with patients who have not presented according to local NHS Board procedures. Dates and times of attempts to contact should be recorded within the smoking cessation support tool. If no response after two missed visits and three attempts of contact then record as lost to follow up in the MDS within PCR and submit it electronically in the time period defined in section 5.2.6. Health boards should be informed of patients who are lost to follow-up through locally agreed protocols.

12-week post-quit date follow-up appointment: the pharmacist or trained member of pharmacy support staff follows the procedure detailed below. This can be carried out between 12 and 14 weeks post quit date.

- Determine the patient's smoking status using the CO monitor to provide feedback. (A reading of less than 10ppm verifies the client as a non-smoker.
- Record the results of the CO reading in the smoking cessation support tool within PCR.
- Congratulate the patient and encourage them to stay quit.
- Electronically submit the MDS data from PCR **immediately** after the appointment but no later than 14 weeks after the quit date.
- Patients who do not attend the arranged appointment should be contacted to reschedule. If no response after three attempts of contact then record as lost to follow up in the smoking cessation support tool within PCR and submit it electronically.
- Health Boards should be informed of patients who are lost to follow up through locally agreed protocols. Boards have until week 16 post quit date to achieve and record a successful follow up directly on the national smoking cessation database.

If at the appointment the patient reports having smoked then the pharmacist or trained member of pharmacy support staff should follow local NHS Board procedures. Where there is no local guidance the pharmacist or trained member of pharmacy support staff should deem the quit attempt to have been unsuccessful if the patient has smoked more than five cigarettes since the 4 week follow up.

Any further cessation support to the patient should be defined as a new quit attempt.

Under these circumstances a **new quit attempt** can be started at any point thereafter based on the professional judgement of the pharmacist. It should be noted however that evidence indicates it is best to allow time to elapse for patients to renew motivation, re-prepare, and have a better chance at a subsequent attempt. Local guidance must be followed regarding the timing of a new quit attempt.

The pharmacist should also determine at this stage whether the patient may have a higher chance of success in any new quit attempt within an alternative more intensive smoking cessation support setting and where appropriate, consider referral to other NHS Board specialist smoking cessation services according to an individual's needs.

Beyond week 12:

Continue to offer support and encouragement when the patient visits the pharmacy

Every attempt should be made to reduce the use of NRT to zero by the end of the 12-week period however if a patient requires NRT beyond the 12-week period the pharmacy service may be extended where local NHS Board guidelines allow in order to titrate down NRT therapy. Alternatively where no local NHS Boards scheme is in place, patients can be advised that they are able to purchase NRT products over-the-counter.

Where a patient requires advice beyond the 12-week period then they should be advised that they can also seek support from local specialist smoking cessation services and the national telephone support line Smokeline on 0800 848 484. The service is open every day from 8am – 10pm and is supported by a website which offers interactive web chat with trained support staff <http://www.canstopsmoking.com/>.

Appendix B - Varenicline Service Procedure

In order to provide support to the patient under this service procedure the pharmacist must have signed the national Patient Group Direction (PGD) for varenicline, completed the NES training and comply with the criteria set out in the PGD.

Varenicline should be used for patients who have attempted to stop smoking unsuccessfully with the assistance of nicotine replacement therapy on one or more previous occasions. Before providing varenicline the pharmacist should complete the varenicline screening tool with the patient to ensure it is appropriate for the patient. Patients supplied with varenicline should be monitored weekly for 12-weeks and provided with additional support and advice on an on-going basis.

The GP should be informed using the standard letter found in the NES pack, <https://www.portal.scot.nhs.uk>. The letter template can be found at http://www.communitypharmacy.scot.nhs.uk/core_services/phs.html

Pharmacists providing support for patients receiving varenicline should ensure that they are able to provide continuity of supply as well as structured support over the 12-week course of the medicine. Patients must be assessed by a pharmacist for suitability of continued treatment with varenicline, but can receive smoking cessation support from a member of pharmacy support staff who has completed the relevant training.

When providing varenicline, the following dose titration schedule should be followed: the recommended dose is 1 mg varenicline twice daily following a 1-week titration as follows:

Days 1 – 3:	0.5 mg once daily
Days 4 – 7:	0.5 mg twice daily
Day 8 – End of treatment:	1 mg twice daily

The patient should set a quit-date. Varenicline dosing should usually start one or two weeks before this date.

Abrupt cessation of varenicline may be associated with an increase in irritability, urge to smoke, depression and insomnia in up to 3% of patients. Dose tapering may need to be considered as the patient approaches the end of their course of varenicline. The most appropriate approach to this may be to titrate the dose downwards, in the opposite direction from the dose tapering at the start of treatment.

Varenicline is known to very commonly cause nausea, insomnia, abnormal dreams and headache. A list of adverse reactions identified for varenicline is found in the Champix SPC (www.medicines.org.uk). As a “Black Triangle” medicine, any suspected side effects or adverse reactions to Varenicline must be reported using the Yellow Card Scheme. It may be possible to manage minor side-effects through a decrease in varenicline dosage.

Pre-quit attempt: when the patient is initially identified the pharmacist follows the procedure detailed below:

- Assess the patient's current smoking status and previous quit attempts (if any). Obtain consent to follow-up the patient, in accordance with local board Caldicott Guardian advice. Record contact details for the patient including telephone numbers
- Ascertain if other options are preferable e.g. group sessions – if so refer to specialist smoking cessation services.
- Check if the patient is motivated to stop smoking.
- Discuss if there are any advantages or disadvantages to not smoking.
- Stress that this is a “Stop Smoking” programme, not a reducing programme.
- Provide written information on both the NRT and varenicline options for the patient to consider.
- Explain the patient pathway and his/her commitment to attend sessions and the requirement to provide a medical history if varenicline is to be used.
- Ask the patient to complete the patient assessment form if they wish to be considered for varenicline.
- Determine the patients suitability for varenicline. If assessed as not suitable for varenicline consider NRT as a treatment option.
- Record the patient's details and motivation to quit in the smoking cessation support tool within PCR. Discuss setting a formal quit date and the need to start varenicline around 7 days before the quit date. Do not set the quit date in the smoking cessation support tool at this stage,
- Arrange an appointment at a mutually convenient time for the patient to return to see the pharmacist to receive a supply of varenicline and further support at least 7 days before the quit date.
- Provide supportive literature 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' and bring back to the pharmacy at week one for discussion.

DO NOT routinely provide varenicline at this visit.

Return appointment -quit date for varenicline supply: when the patient attends the return appointment the **pharmacist** follows the procedure detailed below for the return appointment:

- Determine the patient's initial smoking status using a Carbon Monoxide (CO) monitor according to local guidance.
- Discuss relevant sections of the 'How to Stop Smoking and Stay Stopped' booklet to ensure the patient wants to stop smoking.
- If the patient has been assessed as appropriate to receive varenicline set and record a formal quit date between 1 and 2 weeks after starting varenicline. Supply a varenicline starter pack and explain dose titration. Explain side effects that may be experienced and actions to be taken if they occur. Agree a time to return a few days after pre-agreed quit date.
- Complete a CPUS form for the titration pack. **Patients CHI number must be on the form for payment**
- Record any additional patient data in the smoking cessation support tool within PCR.

- Record the result of the CO reading in the smoking cessation support tool within PCR
- Electronically submit the MDS data detailing the quit date from PCR immediately after the patient appointment.
- Provide advice (both written and verbal) to the patient taking into account national and local guidance.
- All advice and support offered should be in line with evidence based practice as outlined in the National Smoking Guidelines (Scotland)
- Identify triggers for smoking (utilise smoking diary) and suggest changes or avoidance strategies for familiar routines.
- Provide tips to help a quit attempt e.g. :-
 - Remove any temptations by disposing of cigarettes, ash trays and lighters.
 - Get buy-in for quit attempt from family & friends
 - Prepare for the quit day
 - Keep hands busy
 - **BE POSITIVE!**
 - Drink plenty of water and eat fruit and vegetables
 - Encourage exercise
 - Reward themselves if they remain quit
 - Provide Smokeline contact details and encourage the patient to use the service for additional support.

- Explain to the patient the use of the recording of their data on the national database, that by signing the CPUS form they are consenting for data sharing with relevant NHS personnel and that they may be contacted for follow-up at a later date.
- Invite the patient to attend the pharmacy to receive weekly on-going support despite having a received a two week supply of varenicline.
- The 4-week post-quit date session should always be conducted at the appropriate time.
- Advise the patient's GP that their patient has started a "stop smoking" attempt using varenicline.
- Explain to the patient that if they do not attend any arranged appointments they will be contacted to reschedule/ follow-up.
- The smoking cessation support tool within PCR will check for other quit attempts (with quit date confirmed) at other community pharmacies. If another quit attempt has been recorded within the last 12 weeks, irrespective of the status of the quit attempt, a new quit attempt cannot be started. The patient can only undertake a new quit attempt within 12 weeks if doing so at the same pharmacy as the previous attempt.

Subsequent weeks prior to 4-week post-quit date follow-up appointment: the **pharmacist** and/or in the case of providing support a trained member of pharmacy support staff follows the procedure detailed below.

- Ask how the patient "got on" during the past week
- Determine the patient's smoking status at each supply interval using the CO monitor to provide feedback.
- Record the results of the CO reading in the smoking cessation

support tool within PCR.

- Assess compliance with and suitability of product. Reinforce the correct use of varenicline and discuss any concerns about side effects.
- If patient is experiencing side effects consider reducing the dose to 0.5mg twice daily temporarily or permanently or alternatively stopping varenicline and commencing on a course of NRT
- Discuss what has gone well and what has gone less well, coping strategies, support from family, withdrawal symptoms.
- Give practical advice and help in dealing with problems related to the quit attempt.
- Advise on diet e.g. avoid sugary snacks between meals, try fruit or vegetables instead.
- Give encouragement to continue in the quit attempt
- Make subsequent supplies of varenicline (pharmacist only) when necessary using the 28-day pack.
- Arrange follow up appointments at weekly intervals.
- Follow-up patients who do not present as anticipated e.g. through a proactive telephone call or text message. At least **three** attempts should be made to follow-up with patients who have not presented according to local NHS Board procedures. Dates and times of attempts to contact should be recorded within the smoking cessation support tool. If no response after two missed visits and three attempts of contact then record in the MDS within PCR and submit it electronically in the time defined in section 5.2.6.

If the patient does not return in the weeks leading up to the 4-week post-quit date attempt to contact them. If there is no response after two missed visits record that “patient defaulted”, cancel the quit attempt and submit the MDS within PCR.

4-week post quit-date follow-up appointment: the pharmacist or trained member of pharmacy support staff follows the procedure detailed below:

- Determine the patient’s smoking status using the CO monitor to provide feedback.
- Record the results of the CO reading in the smoking cessation support tool within PCR
- Electronically submit the MDS data from PCR **immediately** after the 4-week post-quit date appointment or in accordance with local Board protocols but no later than 6-weeks post-quit date.
- Patients who do not attend the arranged appointment should be contacted. If no response after three attempts of contact then record in the MDS within PCR and submit it electronically.
- Make a supply of varenicline if necessary.
- Arrange follow up appointments at weekly intervals.

If at the 4-week post-quit date follow-up the patient reports having smoked in the last 2 weeks then the pharmacist or trained member of pharmacy support staff should follow local NHS Board procedures. Where there is no local guidance the pharmacist or trained member of pharmacy support staff should deem the quit attempt to have ended and record as unsuccessful in which case further supplies of varenicline should be ceased and any further cessation support

to the patient should be defined as a new quit attempt. In this circumstance once the 4 week submission has been made the quit attempt should be completed in the smoking cessation support tool.

Under these circumstances a **new quit attempt** can be started at any point thereafter based on the professional judgement of the pharmacist as long as the **new quit attempt is undertaken at the same community pharmacy**. It should be noted however that evidence indicates it is best to allow time to elapse for patients to renew motivation, re-prepare, and have a better chance at a subsequent quit attempt. Local guidance must be followed regarding the timing of a new quit attempt.

The pharmacist should also determine at this stage whether the patient may have a higher chance of success in any new quit attempt within an alternative more intensive smoking cessation support setting and where appropriate, consider referral to other NHS Board Specialist Smoking Cessation Services according to an individual's needs.

Any new quit attempt must be recorded as a new smoking cessation tool entry in PCR recording as complete the previous attempt.

Subsequent weeks prior to the 12-week post-quit date follow-up appointment: After the 4-week post-quit date attempt follow-up appointment the pharmacist or trained member of pharmacy support staff follows the procedure detailed below:

- Ask how the patient "got on" during the past week and assess compliance with and ongoing suitability of varenicline
- Determine the patient's smoking status at each supply interval using the CO monitor to provide feedback according to local guidance
- Record the results of the CO reading in the smoking cessation support tool within PCR
- Record an intervention for the patient on PCR.
- Make subsequent supplies of varenicline when necessary at two-weekly intervals.
- Complete a CPUS form for the varenicline including CHI number.
- Discuss what has gone well and what has gone less well, coping strategies, support from family, withdrawal symptoms.
- Continue to give encouragement and advice (both written and verbal) as required by the patient and according to national and local guidance in order to support the quit attempt
- Arrange follow up appointments
- Follow-up patients who do not present as anticipated e.g. through a proactive telephone call or text message. As before, at least **three** attempts should be made to follow-up with patients who have not presented according to local NHS Board procedures. Dates and times of attempts to contact should be recorded in the smoking cessation support tool within PCR. If no response after two missed visits and three attempts to contact then record as lost to follow up in the MDS within PCR and submitted electronically in the time period defined in section 5.2.6. Health boards should be informed of patients who are lost to follow up through locally agreed protocol, within the timeframe specified

to allow for Health Board staff to follow up.

12-week post-quit date follow-up appointment: the pharmacist or trained member of pharmacy support staff follows the procedure detailed below for patients who make it through to being smoke free after 12 weeks:

- Determine the patient's smoking status using the CO monitor to provide feedback. (A reading of less than 10ppm verifies the client as a non-smoker.
- Record the results of the CO reading in the smoking cessation support tool within PCR.
- Congratulate the patient and encourage them to stay quit.
- Electronically submit the MDS data from PCR **immediately** after the 12-week post-quit date appointment or in accordance with local Board protocols but no later than 14 weeks after the quit date.
- Patients who do not attend the arranged appointment should be contacted to reschedule. If no response after three attempts to contact then record as lost to follow up in the smoking cessation support tool within PCR and submit it electronically.
- Health Boards should be informed of patients who are lost to follow up through locally agreed protocols. Boards have until week 16 post quit date to achieve and record a successful follow up directly on the national smoking cessation database

If at the 12 week post-quit date follow-up the patient reports having smoked then the pharmacist or trained member of pharmacy support staff should follow local NHS Board procedures. Where there is no local guidance the pharmacist or trained member of pharmacy support staff should deem the quit attempt to have ended been unsuccessful if the patient has smoked more than 5 cigarettes since the 4 week follow up.

Any further smoking cessation support to the patient should be defined as a new quit attempt.

Under these circumstances a **new quit attempt** can be started at any point thereafter based on the professional judgement of the pharmacist. It should be noted however that evidence indicates it is best to allow time to elapse for patients to renew motivation, re-prepare, and have a better chance at a subsequent attempt. Local guidance must be followed regarding the timing of a new quit attempt.

The pharmacist should also determine at this stage whether the patient may have a higher chance of success in any new quit attempt within an alternative more intensive smoking cessation support setting and where appropriate, consider referral to NHS Board specialist smoking cessation services according to an individual's needs.

Beyond week 12:

Continue to offer support and encouragement when the patient visits the pharmacy

Every attempt should be made to reduce the use of varenicline to zero by the end of the 12 week period however an additional course of 12 weeks treatment with

NHS Circular:
PCA (P) (2014) 12

varenicline at 1 mg twice daily may be considered. This treatment will fall outside this specification and support will not be remunerated.

Where a patient requires additional advice beyond the 12-week period then they should be advised that they can also seek support from the national telephone support line, Smokeline on 0800 848 484. The service is open every day from 8am – 10pm and is supported by a website which offers interactive web chat with trained support staff <http://www.canstopsmoking.com/>.

ⁱ NHS Health Scotland and ASH Scotland (2010). *A Guide to smoking cessation in Scotland 2010*. NHS Health Scotland, Edinburgh. <http://www.healthscotland.com/documents/4661.aspx>

PATIENT GROUP DIRECTIONS FOR SUPPLY OF VARENICLINE ▼ (CHAMPIX[®]) BY AUTHORISED COMMUNITY PHARMACISTS WORKING IN SCOTLAND

(Approved May 2014 - Review Date May 2016)

GENERAL POLICY
PATIENT GROUP DIRECTIONS FOR SUPPLY OF VARENICLINE
STANDING ORDER FOR AUTHORISATION
PATIENT GROUP DIRECTION- SIGNED APPROVAL
APPENDIX 1 - TREATMENT PLAN
APPENDIX 2 – VARENICLINE CLINICAL RISK ASSESSMENT FORM
APPENDIX 3 - LETTERS TO GP

PLEASE REFER TO LOCALISED NHS BOARD VARENICLINE PGD

GENERAL POLICY FOR COMMUNITY PHARMACIST SUPPLYING VARENICLINE ▼ (CHAMPIX®)

Supply of varenicline

Varenicline may be supplied as part of the National Public Health Service (PHS) contract to support quit attempts where the pharmacist has completed the Patient Group Direction (PGD) training relevant to this product. The monthly payments associated with supply in this way will be made through the national scheme. Varenicline must be supplied using a CPUS prescription.

Varenicline is second line to NRT. In order for a client to be considered for varenicline, the client must have tried NRT on more than one occasion for a reasonable time period and have had support from a recognised stop smoking service.

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.

If the GP has to be contacted due to the patient's medical history, in some cases there may be a delay in starting the client on varenicline and the patient should be informed of this.

Accredited Pharmacists

Varenicline may **only** be supplied by an accredited pharmacist. 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.

Approved Premises

The service can only be provided in an approved 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)

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

**PATIENT GROUP DIRECTION FOR SUPPLY OF VARENICLINE ▼ (CHAMPIX®)
BY AUTHORISED COMMUNITY PHARMACISTS**

Indication	Clients accessing the pharmacy smoking cessation service who have tried to stop through a recognised service using NRT with motivational support.
Inclusion Criteria	<ul style="list-style-type: none"> • Dependent smoker (i.e. they smoke within 30 minutes of waking up and /or find quitting unaided difficult) identified as sufficiently motivated to quit • Clients over 18 years of age • The client agrees to receive behavioural support 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 PMR that the patient is unsuitable for varenicline
Exclusion Criteria	<ul style="list-style-type: none"> • Smokers not sufficiently motivated to quit • Client under 18 years of age • Pregnant or breastfeeding women • Sensitivity to varenicline or any of its excipients • Renal impairment (use with caution in elderly patients) • End-stage renal disease • Patients with a history of serious psychiatric illness such as schizophrenia, bipolar disorder and major depressive disorder. • Previous psychiatric illness where pharmacotherapy or psychotherapy had been given • Epilepsy • Patient on theophylline or warfarin • Not to be used in conjunction with other smoking cessation therapies • PMR indicates that the patient is unsuitable for varenicline
Referral criteria	<p>Pharmacists should refer clients to their GP when client is considered eligible for varenicline but supply through pharmacy is not recommended through the exclusion criteria</p> <p>This may include any of the conditions referred to in the exclusion criteria above or previously unrecognised co-morbidities</p> <ul style="list-style-type: none"> • Patients on theophylline due to monitoring that is required • Patients on warfarin • Patients on Antipsychotics (typical and atypical) • Patients with renal failure
Caution	Patients on insulin may be supplied with varenicline. However patients should be advised to monitor their blood glucose level closely

Action if patient declines	Discuss alternative products if suitable and/or offer a referral to the Specialist Smoking Cessation service for further assessment	
Action if Included	Supply varenicline (Champix®) 0.5mg and 1mg tablets.	
Action if excluded	Refer to GP or Specialist Smoking Cessation Service	
Details of treatment course	Drug name	Varenicline ▼ (Champix®) Tablets
	Strength and form	0.5mg and 1mg film coated tablets
	Route	Oral
	Legal status	<ul style="list-style-type: none"> • POM Prescription only medicine • Black Triangle ▼ •
	Dose(s)	<ul style="list-style-type: none"> • 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 0.5mg 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 0.5mg twice daily
Treatment regime	<p>1st consultation (Assessment) Client should set a quit date between the next 8-14 days. Supply 14 day starter pack (11 x 0.5mg tabs with 14 X 1mg tablets)</p> <p>Set a formal quit date between one and two weeks after starting varenicline</p> <p>Take a CO reading</p> <p>2nd Consultation (before quit date)</p>	

	<p>Confirm quit date. Monitor carbon monoxide reading. Supply 1mg varenicline tablets as required.</p> <p>3rd consultation (First follow up). Monitor carbon monoxide reading and confirm abstinence. Supply varenicline tablets as required. (Refer to Appendix 1)</p> <p>Subsequent consultations Supply varenicline tablets if patient has stopped smoking and carbon monoxide reading confirms abstinence. (Refer to Appendix 1)</p> <p>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)</p>
Drug Interactions	<p>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.</p>
Side Effects	<ul style="list-style-type: none"> • Nausea • Sleep disorders/ abnormal dreams • Headache • Appetite changes • Dry mouth /taste disturbances • Drowsiness • Dizziness <p>For less common side effects please refer to BNF</p>
Advice and Support	<ul style="list-style-type: none"> • Advice to clients should include specific product advice on dosage, method of administration and side effects • If client experiences any extreme side effects they should seek medical advice <ul style="list-style-type: none"> - 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 • The major reasons for varenicline failure are: <ul style="list-style-type: none"> - 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: <ol style="list-style-type: none"> 1. Varenicline is not a magic cure: effort and determination are crucial

	<ol style="list-style-type: none"> 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 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; <p>The following general advice should also be given:</p> <ul style="list-style-type: none"> • Follow-up and obtaining further supplies • Possible changes in the body on stopping smoking e.g. weight gain • Effects on driving or using machinery • Patient 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
Informed Consent	<p>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.</p>
Records	<ul style="list-style-type: none"> • 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; • Since varenicline is a 'black triangle drug' 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.
References	<ul style="list-style-type: none"> • British Nation Formulary (BNF) • Summary of Product Characteristics (SPC) for Champix®. www.emc.medicines.org.uk. National Institute for Health and Clinical Excellence. Varenicline for smoking cessation. NICE technology appraisal 123, July 2007. • Medicines and Health Product regulatory Agency (MHRA) safety alert: November 2008

Authorisation

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 of the NHS Board and Proformas 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
1 st week- Assessment week	<p>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)</p> <p>*Make arrangement to see client again before tablets run out i.e. between days 10- 14</p>
3 rd week	<p>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.</p> <p>Supply 1mg varenicline tablets if required Make arrangement to see client the following week</p>
4 th - 12 th week	<p>Monitor carbon monoxide level and check if client has stopped smoking. If client is still smoking, treatment with varenicline should be stopped.</p> <p>If client has quit smoking supply 1mg varenicline tablets as required.</p> <p>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.</p>

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 or breastfeeding?			If ' yes' – refer`
Does client suffer from renal impairment or has end stage renal disease?			If ' yes'- refer
Does client have a history of psychiatric illness (Please refer to PGD)			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
Is client hypersensitive to varenicline or any of its excipients?			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.

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

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)

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)