

**SPECIFICATION  
FOR  
THE PROVISION OF  
VARENICLINE  
IN COMMUNITY  
PHARMACIES**

Original version adapted with kind permission from Worcestershire County Council

## Contents

	<b>Page</b>
1. PURPOSE	3
2. BACKGROUND	3
3. SERVICE PROVISION	3
4. NATIONAL & LOCAL GUIDANCE	4
5. SERVICE STANDARDS & PRINCIPLES	4
6. ACCESS & ELIGIBILITY	5
7. OUTCOMES	5
8. INFORMATION REQUIREMENTS	6
9. TRAINING AND DEVELOPMENT	6
10. QUALITY STANDARDS	6
11. PAYMENT	7
12. PATHWAY FLOWCHART	8

Schedule 1	Stop Smoking Adviser's Form: Request to Pharmacist for an Assessment with a view to Supply of Varenicline (Champix®) under PGD
Schedule 2	Pharmacist's claim form
Schedule 3	Pharmacist's Varenicline Supply Record
Schedule 4	Client's exempt from prescription charge declaration form

## **1 PURPOSE**

- 1.1 This specification is part of the contractual relationship between [insert details] Council (the Council) and community pharmacists (the Service Provider) for the delivery of consultation, assessment and supply of Varenicline.
- 1.2 The Service will only be delivered in accredited community pharmacies across [insert area] by pharmacists who are accredited to provide the service under the Patient Group Direction (PGD) for Varenicline
- 1.3 The aim of the service is to:  
  
Increase the access to treatment for smokers who wish to quit smoking

## **2 BACKGROUND**

- 2.1 Varenicline is a licensed Prescription Only Medicine (POM) as defined by the Medicines Act 1968 and Prescription Only Medicines (Human Use) Order 1997.
- 2.2 Varenicline is subject to standard monitoring arrangements for adverse events via the Yellow Card Scheme.

## **3 SERVICE PROVISION**

### **Stop Smoking Advisers**

- 3.1 The Stop Smoking Adviser will assess the Service User's motivation to quit and provide on-going one to one motivational support throughout the quit attempt. If the Service User expresses a preference for Varenicline the Stop Smoking Adviser will conduct an initial assessment for suitability and, if there are no contra-indications, refer the Service User to an accredited service provider using the form at Schedule 1 of this service specification. The Service User will present the form to the Service Provider.
- 3.2 Alternatively the Stop Smoking Adviser can send the form to the Service Provider.
- 3.3 The Stop Smoking Adviser will provide suitable service users with the current list of accredited service providers and the Service User must confirm to the Stop Smoking Adviser which Service Provider they intend to use so as to allow liaison between the Adviser and Service Provider.
- 3.4 The Stop Smoking Adviser must explain to the Service User that it will be the Pharmacist's decision whether or not to supply Varenicline.
- 3.5 The Stop Smoking Adviser must advise the Service User to access Varenicline through one service provider only to ensure continuity of care and liaison between the Stop Smoking Adviser and the Service Provider. The Service Provider will provide the full course of treatment at agreed intervals together with associated monitoring.
- 3.6 If the Stop Smoking Adviser identifies any cautions they may not proceed with a request for Varenicline for the service user, but may offer NRT.
- 3.7 Please see client held record at Schedule 5. This is to be completed by the stop smoking adviser and then the pharmacist to provide an ongoing update between both services about the client's most recent appointment.

### **The Service Provider**

- 3.7 The Service Provider must ensure that all pharmacists involved in the provision of the service operate within the current Patient Group Direction.

- 3.8 The Service Provider must assess the Service User for suitability for treatment with Varenicline and record the outcome using the form at Appendix 1 of the PGD
- 3.9 In every case, when the initial supply of Varenicline is made in accordance with the PGD, the Service Provider must inform the Service User's General Practitioner of the supply within two working days. This applies whether the pharmacy is a Council Contracted NHS Stop Smoking Service provider or not.
- 3.10 Where the Service Provider is not the Service User's Council contracted NHS Stop Smoking Service provider, the Service Provider must also inform the Stop Smoking Service provider within two working days of the initial supply.
- 3.11 If the outcome of the initial assessment is to not supply Varenicline the Service Provider must inform the Service User's Stop Smoking Service so that an alternative treatment may be offered.
- 3.12 If Varenicline is withdrawn at any stage the Service Provider must inform the Service User's Stop Smoking Service so that an alternative treatment may be offered.
- 3.13 The Service Provider only will provide the full course of treatment and not refer the Service User on to another Service Provider except in unavoidable circumstances e.g. sickness.
- 3.14 The Service Provider shall maintain a record of supply using the form at Schedule 3.
- 3.15 The client's declaration of exemption from prescription charge is at Schedule 4.
- 3.16 Please see client held record at Schedule 5. This is to be completed by the Stop Smoking Adviser and then the pharmacist to provide an ongoing update between both services about the client's most recent appointment.
- 3.17 The pharmacist may decide to restart a patient on Champix within a six month period following a lapse if deemed appropriate. This must be recorded in writing and/ or on the patient medical to explain the reasoning behind this decision, and the Service User's Stop Smoking Service must be notified.
- 3.18 The pharmacist may decide to extend treatment beyond 12 weeks, for example a further 2 weeks, if deemed appropriate.
- 3.19 The pharmacist must supply Champix in an appropriately labelled pack.

#### **4 NATIONAL GUIDANCE**

- 4.1 The Service Provider shall deliver the Service in line with the NHS (Pharmaceutical Services) Regulations 2005 and any other relevant professional standards.
- 4.2 The Service Provider shall take account of any NICE guidelines that are relevant to the Service.
- 4.3 The Service Provider will deliver the Services in accordance with best practice in health care and shall comply in all respect with the standards and recommendations contained in:
  - i. National Service Frameworks and National Strategies
  - ii. National Patient Safety Agency alerts and guidance
  - iii. Human Medicines Regulations 2012
  - iv. and such other quality standards agreed in writing between the Service Provider and the Council.

- 4.4 The Service Provider will at all times comply with the most recent guidance on medicines from the Medicines and Healthcare products Regulatory Agency (MHRA).

## **5 SERVICE STANDARDS AND PRINCIPLES**

- 5.1 The Service Provider will ensure that Standard Operating Procedures (SOPs) are in place for the service and ensure that all pharmacists and members of staff involved in delivering the service are aware of them and work in accordance with them.
- 5.2 Service Users will be seen as individuals, and the Service will be personalised to the needs of the individual and dedicated to promoting the independence, well-being and dignity of every Service User who engages with the Service.
- 5.3 The Service will be accessible to all and will take account of culture, religion, race, gender, age, disability and sexuality. The Service Provider will ensure that it meets legal obligations with regards to all relevant equality and human rights legislation.
- 5.4 All paperwork and completed forms will not be left unattended, and will be stored securely within the pharmacy to maintain confidentiality.
- 5.6 The Service Provider will ensure that information acquired during the course of providing the Service is only shared and disclosed with the consent of the Service User as outlined in the NHS code of confidentiality and other associated documents.
- 5.7 The Service Provider will ensure that there are necessary safeguards for, and appropriate use of, Service User and personal information to ensure that such information is dealt with legally, securely, efficiently and effectively, in order to deliver the best possible high quality care. This will be in accordance with relevant legislation and best practice guidelines such as the Data Protection Act (1998) and the Caldicott Principles.
- 5.7 The Service Provider will not make any significant changes to the Service, without prior consultation with the Council.

## **6 ACCESS AND ELIGIBILITY**

- 6.1 The Service will be available throughout the pharmacy's opening hours (both core and supplementary). The Service Provider will maintain an acceptable level of staffing at all times, and will provide suitably accredited, skilled, trained and experienced staff to provide the Service.
- 6.2 The Service will only be available to Service Users referred by Stop Smoking Advisers with the appropriate authority of a Council contracted Stop Smoking Service provider.
- 6.3 The Service will be provided that assesses the suitability for a Service User to receive Varenicline to ensure they meet the Patient Group Direction criteria as set out in the PGD.
- 6.4 The Service Provider will provide advice to the Service User.
- 6.5 Service Users excluded from the PGD criteria: if the Service Provider is a Council contracted NHS Stop Smoking Service and currently supporting the Service User to quit, the Service User should be offered the option of NRT or, if the Service User still expresses a preference for Varenicline, they should be referred to their GP (see PGD). Other Service Providers should direct the Service User back to their original council contracted NHS Stop Smoking Service provider (see PGD).
- 6.6 The Service Provider will ensure that the part of the pharmacy used for the provision of the service provides a sufficient level of privacy for the Service User.
- 6.7 The service will be available to Service Users over 18 years of age who meet the inclusion criteria detailed in the PGD.

## **7 OUTCOMES**

7.1 The Service will contribute towards the following outcomes:

- i. Help increase the number of smokers who successfully quit smoking, and thereby reduce the prevalence of smoking in [\[insert area\]](#).
- ii. Improve and increase access to Varenicline.

## **8 INFORMATION REQUIREMENTS**

8.1 Records will need to be kept by the Service Provider to enable an audit trail to be undertaken. The Council will periodically request this information in addition to regularly monitoring the monthly claims for payment submitted to the Council.

8.2 The Service Provider will participate in any surveys as directed by the Council.

8.3 The Service Provider will participate in any audits of the Service as directed by the Council.

## **9 TRAINING AND DEVELOPMENT**

9.1 The Service Provider shall ensure that all pharmacists involved in the provision of the service have relevant knowledge and have completed the required training:

- i. Pre-course reading and self-assessed test: the pharmacist must submit a signed statement to the Council to confirm they have completed this requirement.
- ii. Ensure that all pharmacists involved in the provision of the service have relevant knowledge of Patient Group Directions and have considered any personal development needs in the relation to their use.
- iii. Completed a Council approved Varenicline training session and been awarded a certificate of completion.
- iv. Be aware of local Child Protection guidance available at:- [\[insert link to local guidance\]](#)

9.2 The Service Provider must ensure that all medicine counter staff are trained to refer each request for Varenicline treatment to the pharmacist. If an accredited pharmacist is unavailable, staff should be trained to arrange for patients to see an accredited pharmacist within the pharmacy at a time suitable to the patient (after first checking when an accredited pharmacist is available).

9.3 Inform the Council of any changes to personnel relating to accredited pharmacists as soon as possible and no later than 2 weeks after this change has occurred.

9.4 All staff involved in the delivery of the Service must attend any additional training as directed by the Council.

9.5 The Service Provider shall provide evidence of the completion of the above training upon request by the Council.

## **10 QUALITY STANDARDS**

10.1 The Service Provider will have robust risk management process in place, including:

- i. Incident reporting and investigation processes
- ii. Complaints processes.

10.2 The Service Provider will report all serious untoward incidents to the Council and provide details of recommendations and actions taken as a result.

## **11 Payment**

11.1 The fee payable for the first supply is higher than the subsequent supply fees to acknowledge the additional checks required prior to the first supply.

11.2 The relevant cost of the drug at current Chemist and Druggist list price (C&D) is also payable.

11.3 The prescription fee will be deducted from payment if collected.

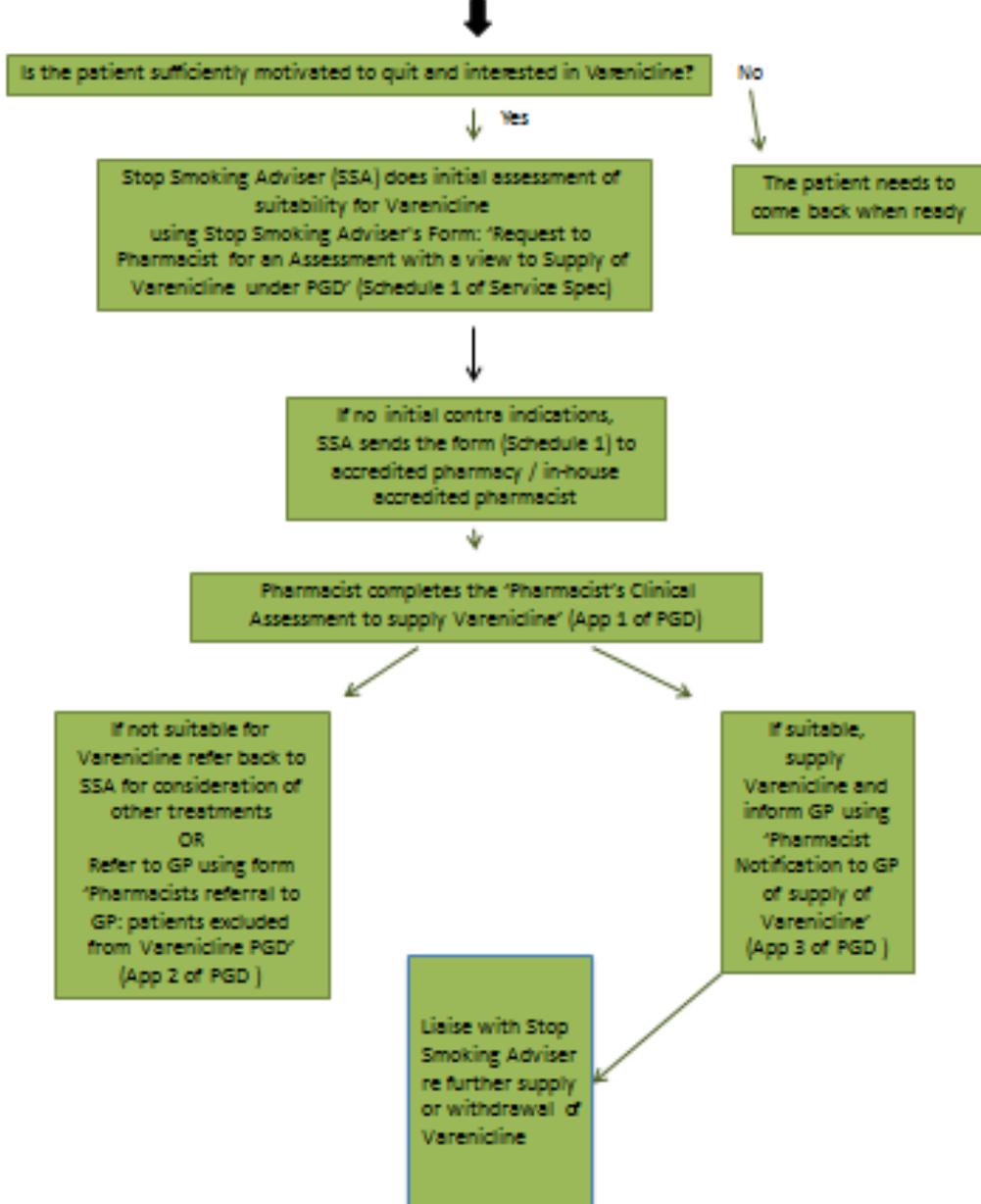
11.4 Claims for payment must be made by submitting the Pharmacist's Claim Form at Schedule 2 of this service specification, fully completed and stamped, monthly.

11.5 The fees payable as at 1.12.13 are as follows:

First supply fee	£XX.00
Subsequent supply fees	£XX.00

11.6 The pharmacist's claim form for payment is available at Schedule 2 of this appendix.

## Client chooses Varenicline with Stop Smoking Adviser (SSA)



**Schedule 1**

**Stop Smoking Adviser's Form: Request to Pharmacist for an Assessment with a view to Supply of Varenicline (Champix®) under PGD**  
**PLEASE PHOTOCOPY FOR FUTURE USE**

Client Name DOB

Client Address Post code

**Is the client sufficiently motivated to stop smoking?      Yes      No**

If no, DO NOT continue with this form to request supply of varenicline - advise the client to return when they are ready to make a quit attempt.

**Criteria for Exclusion**

Is the service user under 18 years old? Yes       No

Is the service user pregnant? Yes       No

Is the service user breastfeeding? Yes       No

Does the service user have epilepsy? Yes       No

Any known allergies (please list).....No

If the service user answers yes to any of the above then varenicline may not be suitable.

Other options available to the client are:

- offer NRT
- refer client to their GP if the client still expresses a preference for varenicline

If in doubt seek further advice from the client's GP.

If the client answers no to all the above questions send this form, or ask the client to take this form, to an accredited pharmacy of the client's choice from the list of accredited pharmacies.

**Name of Adviser:** **Role:**

**Stop Smoking Service:** **Service Address:**

**Postcode:** **Tel no:**

**Signature:** **Date:**

**Please note it will be at the discretion of the accredited pharmacist to supply Varenicline taking account of the client's medical history. The pharmacist will contact the Stop Smoking Adviser to inform whether or not Varenicline has been supplied.**

# Pharmacist's Champix Claim Form

Pharmacy Name and Address :	Month and year:
-----------------------------	-----------------

Consultation Date	Service User Postcode	Client Date of Birth	Exemption from prescription charge? (✓)	Claim initial supply fee? (✓)	Claim follow up fee? (✓)	Pharmacists Name (Please print)
		<b>Total:</b>				

	Number	Fee per supply	Total Value
Initial supply fees @ £XX per supply		£XX	
Follow up supply fees @ £XX per supply		£XX	
Number of Champix starter packs (at current C&D list price)			
VAT @ 5% for starter packs supplied			
Number Champix follow up packs (at current C&D list price)			
VAT @ 5% for follow up packs supplied			
<b>Sub-total</b>			
Deduct number and value of prescription charges collected (value to be deducted from sub-total)			
		<b>Total Claim (£)</b>	

Pharmacy stamp:

**PLEASE PHOTOCOPY FOR FUTURE USE**  
 Please return completed forms within 7 days of the end of each month to:  
 [insert address]

Schedule 3

**Pharmacist's Varenicline Supply Record**

<b>Date</b>	<b>Supplied</b>	<b>Batch number</b>	<b>Expiry date</b>	<b>Confirm client seen by Stop Smoking Adviser for behavioural support since last supply – insert date or ✓</b>	<b>Notes e.g. advice given, adverse effects</b>
	Starter pack				
	Follow on pack				

**Schedule 4**

**Supply of Varenicline under PGD**

**Client's exempt from prescription charge:  
Client declaration form**

**Client exemption status**

- I am under 16 years of age
- I am 16, 17 or 18 and in full time education
- I am 60 years of age or older
- I have a valid maternity exemption certificate
- I have a valid medical exemption certificate
- I have a valid prescription pre-payment certificate
- I have a war pension exemption certificate
- I am named on a current HC2 charges certificate
- I get income based jobseekers allowance
- I get income support
- I have a partner who gets PCGC
- I am entitled to, or named on a valid NHS tax credit exemption voucher

Client's name.....  
Address.....  
Postcode.....Date of birth.....  
Date: .....

I have received a supply of Varenicline (Champix). I declare that the information I have given on this form is correct and complete.

Client's signature .....

**Prescription fee collected?**      Yes       No

**Schedule 5: Client held record: Stop Smoking Support and Champix supply through Pharmacy PGD**

To be completed by the stop smoking adviser and the pharmacist to provide an ongoing update between both services about the client's most recent appointment

**Client's name**.....**Quit Date**.....

**Address**.....**Post code**.....

**Client's Tel number**.....**Mobile**.....**DOB**.....

**Stop Smoking Service Provider**.....**Adviser's name**.....

**Stop Smoking Clinic site/address**.....

**Stop Smoking Adviser's Tel number**.....

**Champix Supplying Pharmacy name** .....

**Address**.....**Postcode**.....

**Tel number** .....**Pharmacist's name**.....

Date	Stop Smoking Adviser or Pharmacist's name	Actions agreed/comments	Champix supply notes	Date of next appointment	Signature

