

# Service Specification

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## **For the Supply of Varenicline via a Patient Group Direction (PGD)**

Stoke-on-Trent City Council

**Date**            Effective from 1 January 2019

**Lead Officer**   Rochelle Edwards

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## DEFINITIONS

Accredited Stop Smoking Provider	A Provider who has been awarded a contract by the Authority to deliver stop smoking support across Stoke-on-Trent City Council.
Centre for Pharmacy Postgraduate Education (CPPE)	A provider of educational solutions for the NHS pharmacy workforce across England to maximise its contribution to improving patient care.
Declaration of Competence	The Declaration of Competence (DoC) system has been developed by the CPPE to help registered pharmacy professionals (pharmacists and pharmacy technicians) to deliver sustainable quality pharmacy services to patients. It provides a self-assessment framework which enables pharmacy professionals to assure themselves, the Authority and employers that they are competent and meet the requirements to provide a service. It is supported by a robust learning and assessment pathway.
Direct Supply	Direct Supply is the supply of NRT products provided directly from the Accredited Stop Smoking Provider to the Treated Smoker
General Pharmaceutical Council (GPhC)	The General Pharmaceutical Council (GPhC) is the independent regulator for pharmacists, pharmacy technicians and pharmacy premises in Great Britain
National Pharmaceutical Association (NPA)	Supports community pharmacist as a not-for-profit organisation, committed to reinvesting in service provision
National Reporting and Learning System (NRLS)	Work to identify and reduce risks to patients receiving NHS care. As well as lead on national initiatives to improve patient safety.
PharmOutcomes	A data management system which the Pharmacist will use to collect Service User information when supplied with Varenicline
Patient Group Direction (PGD)	PGDs provide a legal framework that allows some registered health professionals to supply a specified medicine to a pre-defined group of patients without them having to see a doctor.
Quit Date	The date on which a Smoker plans to stop smoking altogether with support from a stop smoking adviser as part of an NHS-assisted quit attempt.
Service User	A person who smokes and accesses an accredited stop smoking provider for support
Smoker	A person who smokes a smoked product. In adulthood this is defined in terms of daily use, whereas in adolescence (i.e. for those aged 16 or under) it is defined in terms of weekly use.
Stop Smoking Advisor	An individual who has completed the required approved training outlined in the service specification, and is employed by a provider commissioned by the Authority to deliver the Stop Smoking Service.
Summary of Product Characteristics	A description of a medicinal product's properties and the conditions attached to its use
Treated Smoker	A Smoker who has received at least one session of a structured, multi-session intervention (delivered by a stop smoking adviser) on, prior or just after the Quit Date, who consents to treatment and sets a Quit Date with a stop smoking adviser. Smokers who attend a first session but do not consent to treatment or set a Quit Date should not be counted
Varenicline (trade name Champix)	A prescription only drug used to help smokers to quit by mimicking the effects of nicotine on the body
Yellow Card Scheme	Any adverse drug reactions are reported via the yellow card system. The yellow card scheme enables the monitoring and safety of all healthcare products in the UK to ensure they are acceptably safe for patients and those that use them

## Introduction

The purpose of the tender is to accredit Pharmacies, which can provide access to Varenicline via a Patient Group Direction (PGD) to Service Users accessing the Stoke-on-Trent Stop Smoking Service. The Service is City wide therefore multiple Pharmacies will be accredited across Stoke-on-Trent to ensure Service Users have easy access to Varenicline. Training for this service is self-accreditation. Pharmacists will be responsible for ensuring they meet the relevant accreditation and training requirements set out within this specification. The supply of Varenicline via a PGD will help Service Users to quit and support the Authority to reduce levels of smoking-related illness, disability, premature death, and health inequality. This element of the Stop Smoking Service will be delivered in-line with the most recent best practice recommendations issued by the National Institute for Health and Clinical Excellence (NICE), the National Centre for Smoking Cessation Training (NCSCT) and PGD legislation and guidance.

## Background

The Authority wishes to ensure competent Pharmacists are available, across the City of Stoke-on-Trent, to supply Varenicline via a Patient Group Direction (PGD) (see Appendix 1) to Service Users accessing the Stoke-on-Trent Stop Smoking Service. The Stop Smoking Service sits within an overall tobacco control programme and forms part of a wider action to reduce local smoking prevalence.

The aim of Stop Smoking Services is to reduce the number of Smokers by providing evidence-based treatment and behavioural support to Smokers making quit attempts. Treatment includes the provision of stop smoking medication. The only types of stop smoking medications currently licensed for use are: Nicotine Replacement Therapy (NRT), bupropion (Zyban) Varenicline (Champix) and Voke. Only NRT, bupropion and Varenicline are available to Service Users accessing the Stop Smoking Service. Varenicline or combination NRT offer smokers the best chances of quitting and, unless clinically contraindicated, should be available as first-line treatments to all clients<sup>1</sup>. NRT is available from Accredited Stop Smoking Providers via Direct Supply and is part of the stop smoking contract; it is therefore outside the scope of this specification. This specification is only concerned with Varenicline as it is a prescription only medication and has been identified by the Authority as difficult to access for Service Users. Therefore a more accessible pathway is needed for Service Users to access the drug. A PGD was deemed to be the most appropriate route for supplying Varenicline as PGDs provide a legal framework that allows some registered health professionals to supply a specified medicine to a pre-defined group of patients without them having to see a doctor.

## Premise Requirements

Pharmacies providing this Service will meet the following requirements:

- Pharmacies will be located within the Stoke-on-Trent Local Authority boundaries.
- The Authority wishes to ensure that Pharmacies are based in a variety of locations across the City of Stoke-on-Trent which are easily accessible and suitable for eligible Service Users.
- Service provision should be carried out in suitable premises for private consultations.

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<sup>1</sup> NCSCT: Local Stop Smoking Services Service and Delivery Guidance (2014)

- Consultations will be provided in a safe and suitable environment, and not where potentially sensitive questions may be asked and may be overheard (in waiting area, for example). The reception, waiting and treatment areas should be accessible, comfortable and welcoming.
- The Pharmacy should be accessible to wheel-chair users and other users with a physical disability.
- The Pharmacy staff should be sensitive to the cultural needs and backgrounds of Service Users accessing Varenicline.
- The Pharmacy must have access to PharmOutcomes to record the data and claim reimbursement.
- Where reasonably possible, adequate staffing arrangements will be in place to enable the full supply of Varenicline to be provided to the Service User at the same Pharmacy.
- All Pharmacy staff will have access to information on all Pharmacies which have been accredited to ensure that in the event of an unexpected absence by an accredited Pharmacist Service Users can be referred on appropriately.
- The opening times of the service will be determined by the Pharmacy but must be when there is an accredited Pharmacist available to supply Varenicline. The Authority is looking for a range of opening times which will enable Service Users to access Varenicline at a time that is convenient to them. The Pharmacy owner or the Pharmacist must notify the Authority of any planned changes to service opening times.
- The Pharmacy owner must notify the Authority if a Pharmacist moves Pharmacies or leaves.
- The Pharmacy owner must notify the Authority where a Pharmacy closes or relocates.

## Pharmacist Requirements

Pharmacists supplying Varenicline via a PGD will meet the following requirements:

- Be working in a Stoke-on-Trent Pharmacy (as defined by the Authority boundaries or as agreed by the Authority to meet the demands of the Service) which has a suitable private consultation room.
- Will provide an appointment for Service Users wishing to receive Varenicline within 48 hours of being contacted by the Service User or accredited Stop Smoking Provider and that all staff within the Pharmacy are aware of this.
- Will ensure that their professional indemnity cover is provided by the National Pharmaceutical Association (NPA) or other organisation which has confirmed that this activity is included in their policy.
- Be a fully registered member of the General Pharmaceutical Council (GPhC).
- Will be registered with the Centre for Pharmacy Postgraduate Education (CPPE).
- Will be able to demonstrate their competencies for supplying Varenicline via a PGD through a self-accreditation process. This will include completing the CPPE Declaration of Competence (DoC) which will provide assurance to the Authority that:
  - a comprehensive and demonstrative system of clinical governance is in place
  - a system is in place to submit reports of patient safety incidents to the National Reporting and Learning System (NRLS) the Authority and NHS Area Team
  - Standard Operating Procedures (SOP) relevant to the provision of this service are in place

- there is a good understanding of smoking cessation in place
- Will supply Varenicline in accordance with the PGD set out in Appendix 1 which is subject to change/updates by the Authority at any time.
- The Pharmacist must comply with the Equality Act 2010. The Pharmacist must abide by the Caldicott principles, Data Protection Act 1998 and any later version of this legislation, the General Data Protection Regulation (GDPR) and the Freedom of Information Act 2000 in the handling and security of information, ensuring that it is kept accurate, up to date and kept only for as long as needed for the specified purpose
- At the initial appointment the Pharmacist will book in advance subsequent appointments with the Service User.
- If Pharmacists are aware of a planned leave of absence which will affect a Service Users ability to access subsequent supplies of Varenicline this must be accounted for through either ensuring another accredited Pharmacist is available within the same Pharmacy or ensuring an appointment is made with another accredited Pharmacist in a different Pharmacy.

Please note:

- Locum Pharmacists who are not accredited to supply Varenicline cannot provide cover for this service in the absence of the accredited Pharmacist
- It is not a pre-requisite for Pharmacists to be a Stop Smoking Provider in order to apply for this contract
- Pharmacists who are Accredited Stop Smoking Providers (including through subcontracting arrangements) can apply for the contract. If the application is successful Varenicline can be supplied to both Service Users accessing behavioural support from the Pharmacy as well as Service Users accessing stop smoking support from other Accredited Stop Smoking Providers.

#### Pharmacist Training and Accreditation

Training for this service is self-accreditation. Pharmacists are expected to map their competencies to the Stop Smoking DoC and are expected to access any training they deem necessary in order to meet the competencies. In addition, all Pharmacists will need to read and complete the following;

- Complete the CPPE e-learning - Stop Smoking: very brief advice and its related assessments
- Complete the CPPE e-learning - Patient Group Directions and its related assessments
- Read and understand the PowerPoint Presentation agreed by the Authority (available on the LPC <https://www.northstaffslpc.co.uk/>)

The following steps will need to be taken by the Pharmacist to ensure the DoC is valid and enable access to PharmOutcomes:

- Download the Stop Smoking DoC from the CPPE website ([www.cppe.ac.uk/doc](http://www.cppe.ac.uk/doc)) and complete with above information and any other training or assessments that have been completed.
- Print, sign and date to acknowledge professional responsibility and demonstrate competence to provide the service. Note that only printed and physically signed DoCs are valid.
- Save DoC in the service folder, within the Pharmacy, ready for inspection by the commissioner at any time.
- Access CPPE record and confirm that the DoC has been signed.
- The PGD must also be signed and stored with the DOC ready for inspection by the commissioner

at any time

#### Volume

It is expected that between 750 to 900 Service Users who access the Stop Smoking Service will request and be suitable for Varenicline each year. Not all these Service Users will use the full supply of Varenicline.

#### Accessibility/acceptability

Varenicline will only be supplied to Service Users accessing the Stoke-on-Trent Stop Smoking Service. Pharmacists should only accept Service Users who provide a letter from an accredited Stop Smoking Provider at their initial appointment (see Appendix 1). This letter will include a unique supply reference code which will need to be entered onto PharmOutcome, to check against fraudulent claims. PharmOutcomes will not allow the Pharmacy to save a supply if the unique reference number has already been used in another supply. If the system identifies that the code has already been used the Authority and the Stop Smoking Provider should be informed immediately. If this occurs during the consultation then the Service User should not receive the supply.

The Pharmacist will provide an appointment within 48 hours of being contacted by the Service User or Accredited Stop Smoking Provider.

Pharmacists who speak different languages are encouraged to apply to ensure Varenicline can be supplied to Service Users where English may not be their first language.

#### Inclusion and Exclusion criteria

Before supplying Varenicline, the Pharmacist must confirm the criteria for inclusion and ensure any exclusions do not apply (as set out in sections 2.2 and 2.3 of Appendix 1)

If a Provider has concerns about the suitability of a Service User that has been referred to the service, the Provider must inform the Accredited Stop Smoking Provider within 2 working days.

#### Referral Route

Only Service Users referred by an Accredited Stop Smoking Provider can receive Varenicline via the PGD. The initial referral will be via a telephone call to make an appointment with the Pharmacists. The Service User will submit a letter at the first appointment to confirm that they are receiving support and have set a quit date.

#### Response time & detail and prioritisation

The Pharmacist must arrange an appointment with the Service User within 48 hours of receiving the telephone call to make an appointment. If no suitable appointments can be found the Service Users should be referred back to their Stop Smoking Provider who will identify a different Pharmacist.

The Pharmacist must provide clear information on where the Service User can seek help if they feel unwell in-between appointments.

#### Description of Treatment

The treatment regime is fully described in the PGD set out in Appendix 1.

Service Users should be informed that major reasons for Varenicline failure are:

- Unrealistic expectations
- Lack of preparation for the fact that the tablets may cause nausea
- Insufficient or incorrect use

It is important to make sure that the client understands the following points:

- Varenicline is not a magic cure - effort and determination are crucial
- It works by acting on the parts of the brain which are affected by nicotine in cigarettes
- It does not remove all temptation to smoke, but it does make abstinence easier ('it takes the edge off the discomfort')
- Varenicline is safe, but about a third of clients may experience mild nausea some 30 minutes after taking it. This reaction usually diminishes gradually over the first few weeks, and most Service Users tolerate it without problems. If a Service User is unable to tolerate due to nausea refer to GP for full review and/or dose reduction.
- Instruct on correct use and daily dose. Use mock product packaging for the explanation. Service Users should take Varenicline for 7 to 14 days before stopping smoking.
- At the end of treatment, discontinuation of Varenicline has been associated with an increase in irritability, urge to smoke, depression, and/or insomnia in up to 3% of Service Users. The pharmacist should inform the Service User accordingly and discuss or consider the need for dose tapering.
- No clinically significant 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 dose adjustment

In all circumstances dosing should follow the recommendations in the Varenicline Summary of Product Characteristics <http://www.medicines.org.uk/emc>

- Service Users should be supplied a 14 day initiation pack and should have set a target quit date 7 to 14 days after initiation.
- Only 14-day prescription packs, supplied complete with Patient Information leaflet should be used throughout the quit attempt.
- The normal treatment course is 12 weeks.
- An additional course of 12 weeks treatment with Varenicline at the current dose (0.5mg or 1 mg) twice daily may be considered for maintenance of abstinence in exceptional cases with

- permission from the commissioner.
- The maximum length of treatment is 24 weeks.

## Instructions on Identifying, Managing and Reporting Adverse Drug Reactions

Appendix 1 section 3.7 of the PGD describes the common and very common adverse reactions of taking Varenicline:

Any adverse reactions should be reported to the GP. A copy of the information reported using the yellow card system should also be emailed to the Authority using the following email address [stopsmoking@stoke.gov.uk](mailto:stopsmoking@stoke.gov.uk). This should only be anonymised data to comply with data protection and GDPR requirements.

## Actions and communication

### Action if Service User is excluded:

If the GP has informed the Pharmacist that the Service User should not receive the medication, as a result of the email notification or letter (described in section 2.4) then the Pharmacist should use the letter in Appendix 5 to inform the Service User.

Pharmacists which are also Accredited Stop Smoking Providers should offer Service Users the option of NRT.

Where a Service User has been referred by an Accredited Stop Smoking Service they should be referred back to the service. Pharmacists should notify the Accredited Stop Smoking Provider by telephone within 2 working days with an explanation as to why the Service User was excluded. This should be recorded onto PharmOutcomes.

Document action in patient medication record (PMR).

### Action if treatment is declined by Service User

Pharmacists providing Stop Smoking Services should offer other available smoking cessation options if appropriate.

Where a Service User has been referred by an Accredited Stop Smoking Service they should be referred back to the service. Pharmacists should notify the Accredited Stop Smoking Provider by telephone within 2 working days with an explanation as to why the treatment was declined. This should be recorded onto PharmOutcomes. Document action in patient medication record (PMR)

### Action if Pharmacist is unavailable to supply subsequent supplies of Varenicline

After the initial supply of Varenicline the Service User should normally receive subsequent supplies from the same Pharmacy by an accredited Pharmacist. The records for the Service User are specific to the Pharmacy and if a different, service accredited, Pharmacist carries out a subsequent supply they

should view the initial consultation record on PharmOutcomes to confirm that this was completed to their professional satisfaction. Where a Service User is not able to use the same Pharmacy for subsequent supply, for example due to sickness absence then the Service User can attend another participating Pharmacy. In this situation the 'new' Pharmacist will need to re-assess the suitability for Varenicline.

### Communication

In every case when the initial supply of Varenicline is made in accordance with this PGD, the Pharmacist must inform the Service User's General Practitioner of the supply within two working days. This will be done through secure nhs.net email accounts via PharmOutcomes (see Appendix 1 for an exemplar of the information which will be sent).

As per section 2.4 of Appendix 1 where a dose adjustment of current medication is required the Service User should be advised to contact their GP or appropriate clinic to discuss.

Pharmacists should ensure that all matters which affect the Service Users quit attempt are communicated to the Accredited Stop Smoking Provider who made the referral. Contact details of the Advisor providing the behavioural support will be displayed on the referral letter (see Appendix 1a and 1b contained within the PGD)

Pharmacists must advise Service Users and if possible a family member or carer what action to take in the event of the Service User experiencing any side effects and the most appropriate action.

### Discharge

Service Users will be discharged from the stop smoking service by the Accredited Stop Smoking Provider when one of the following occurs;

- A referred Service User is found not to be eligible for the service
- The Service User completes the 12 week service and successfully stops smoking
- The Service User completes the 12 week service but does not stop smoking
- The Service User informs the Stop Smoking Advisor that he/she no longer wishes to receive the service
- Service Users who fail to attend their behavioural support sessions with the Stop Smoking Advisor will be discharged after 3 failed contacts and will be notified accordingly.

When the Pharmacist experiences one of the following the Accredited Stop Smoking Provider should be notified within 2 working days,

- The Service User fails to attend their appointment for Varenicline. Note: it is the Accredited Stop Smoking Providers responsibility to make 3 attempts to contact the Service User.
- The Service User informs the Pharmacist that he/she no longer wishes to receive the service

Pharmacists should ensure good communication between themselves and the Accredited Stop Smoking Provider. Contact details of the Advisor providing the behavioural support will be displayed on the

referral letter. In circumstances where the Advisor is not available the Service Manager should be contacted. A decision will be made by the Accredited Stop Smoking Provider whether the Service user will be discharged.

Note: A Service User may re-access the Stop Smoking Service and therefore request a further supply of Varenicline. Acceptance back into the Service is at the discretion of the Accredited Stop Smoking Provider.

Action if Service User is excluded or treatment is declined by Service User-as per PGD (Appendix 1)

Pharmacists who are also Accredited Stop Smoking Providers should offer Service Users the option of NRT if the Service User is excluded.

Where a Service Users who has been excluded from using Varenicline and has been referred by an Accredited Stop Smoking Provider they should be referred back to this provider. This must be done within 2 working days.

The Pharmacist may need to also inform the Service Users GP as a result of any of the conditions referred to as exclusion criteria above, but also previously unrecognised co-morbidities. Document action in patient medication record (PMR) and inform the Service users GP within 2 working days.

#### Sub-Contracting

Sub-contracting (material or otherwise) is not permitted within the specific group that the Pharmacists have been commissioned to work with.

#### Interdependency

The Pharmacist must work with the Accredited Stop Smoking Provider who has made the referral to ensure the best possible outcome for the Service User.

#### Service Conditions and Environmental Factors

##### **Skilled and welcoming staff**

All Pharmacists must complete the appropriate training in line with individual competencies and local requirements.

All Pharmacists and other Pharmacy staff must provide accurate advice and treatment to all Service Users. Pharmacists recruited to this service will be able to:

- boost Service Users motivation and self-efficacy
- build rapport with Service Users
- use reflective listening
- provide reassurance
- be non-judgemental

- inform Service Users of how to make comments, compliments or complaints
- inform Service Users of how to access other lifestyle/wellbeing services and provide appropriate referrals

The Pharmacist may wish to encourage the Service Users to refer eligible friends and family members to the Stop Smoking Service on 0800 085 0928.

### Statement of Requirements (Monitoring requirements)

#### Key Performance Indicators

<i>Performance Indicator</i>	<i>Indicator</i>	<i>Threshold</i>	<i>Method of Measurement</i>	<i>Frequency of Monitoring</i>
Appointment for Service User	% of Service Users who received an appointment <b>within 48 hours</b> of contacting the Pharmacist	100%	Provider to collate and submit as part of the Quarterly Service Quality performance Report	Quarterly
Data Management	% of Service Users who's data has been entered onto PharmOutcomes <b>within 48 hours</b> following their appointment.	100%	Provider to collate and submit as part of the Quarterly Service Quality performance Report	Quarterly
Communication with GP	% of GPs who were informed <b>within two working days</b> of their patient receiving an initial supply of Varenicline	100%	Provider to collate and submit as part of the Quarterly Service Quality performance Report	Quarterly
Communication with Accredited Stop Smoking Provider (where applicable)	% of Accredited Stop Smoking Providers who were informed <b>within 2 working days</b> that the Service User failed to attend their appointment for Varenicline, or who informed the Pharmacist that they no longer wish to receive the Service	100%	Provider to collate and submit as part of the Quarterly Service Quality performance Report	Quarterly
Service User Experience	% who received a questionnaire	95%	Provider to collate and submit as part of the Quarterly Service Quality Performance Report	Provider to submit information on incident
	% who responded to the questionnaire	20%		
	% reporting that they were satisfied with the service	80%		

The Pharmacist should also ensure that the following are reported to the Authority on a quarterly basis

- Number of starter packs of Varenicline supplied under the PGD
- Number of incidents reported
- Number of complaints received
- Number of compliments received

The Pharmacist will be monitored on the above on a quarterly basis.

The Pharmacist will be audited (at any point deemed necessary by the Authority) through Service User experiences, in a variety of ways such as:

- Mystery shopping programme
- Service User stories
- Service User satisfaction questionnaires

The Pharmacist will be expected to submit an updated DoC as and when required as part of an audit by the Authority:

The Pharmacist will be expected to attend performance review meetings. Short notice meetings may also be required as a result of an incident or complaint that has arisen

## **Deadlines**

Deadlines for submission of KPIs will be made available once the contract is signed. The Pharmacist will be expected to meet these deadlines.

## Technology, systems and management techniques

### **Data Management System**

The Authority will commission a data management system called PharmOutcomes to support data entry and there will be a number of mandated fields that will need to be completed on the system by the System User to ensure the correct data is collected and payment can be made.

A record of each Service Users' personal and medication details must be entered onto PharmOutcomes to enable a full audit trail of the Service User as well as for payment purposes for the Pharmacist. Data to be collected includes (note this is not an exhaustive list):

- Name, address, date of birth and GP details of Service User
- Client ID (note this will appear on the referral letter from the Accredited Stop Smoking Provider). If the Accredited Stop Smoking Provider is the Pharmacist the ID number will be the same that is generated via the data management system for the stop smoking service)
- Unique supply reference code
- Date drug supplied, batch number and expiry date
- Name of Pharmacist
- Name of Advisor and the Accredited Stop Smoking Provider who referred (where applicable)
- Reason for inclusion

- Whether the Service User is entitled to free prescription charges and if so whether evidence has been seen
- Advice given to Service User
- Details of any adverse drug reaction and actions taken
- Completion of contract in line with GDPR requirements

It is expected that all data is entered on the system as near to the activity taken place as possible, to ensure that accurate data information is available to the Authority at all time and **within 48 hours** following the appointment with the Service User. A list of deadlines for submission of data and submitting invoices will be made available by the Authority.

The Pharmacist will take responsibility for the entering and management of their data and the accuracy at all times. Ensuring that the validity of the data is high and quality checks are undertaken.

## Quality Requirements

### Quality Standards for prescribing of Varenicline

- Only Service Users being treated by the Stoke-on-Trent Stop Smoking Service are supplied
- Varenicline is only supplied where clinically appropriate and safe to do so
- All Pharmacists supplying via a PGD keep themselves competent and up to date in accordance with their professional registration requirement and CPPE
- Varenicline is only supplied within the Summary of Product Characteristics and licencing
- Appropriate action is taken to monitor Service Users' conditions and adjust does of medications where necessary
- Any adverse drug reactions are reported via the yellow card system The yellow card scheme enables the monitoring and safety of all healthcare products in the UK to ensure they are acceptably safe for patients and those that use them
- A clear audit trail is in place

### General Quality Standards

- Be responsible for the recruitment, training, support, management, appraisal and supervision of their own Staff and the overall management of the programme.

- Ensure that Staff delivering the service are suitably qualified and if applicable are registered with, and have completed, their revalidations by the appropriate regulatory body.
- Have a nominated member of Staff responsible for safeguarding issues.
- Ensure the service has a level of staffing that ensures a consistent standard of delivery and reflects the value of the Contract.
- Comply with and meet the minimum requirements set out by the Stoke-on-Trent Safeguarding Children's Board (SCB) which can be found here:

[www.safeguardingchildren.stoke.gov.uk](http://www.safeguardingchildren.stoke.gov.uk)

and the Staffordshire and Stoke-on-Trent Safeguarding Adults Partnership Inter-agency Adult Protection Procedures which can be found here:

<http://www.stoke.gov.uk/ccm/navigation/social-care/adult-social-care/safeguarding-vulnerable-adults/>

- Have a recruitment process in place that complies with current Disclosure and Barring Service checks.
- Have in place details of staffing arrangements and contingency planning.
- Ensure the service is sensitive to the cultural, language and backgrounds of the different audiences it is delivering messages to and tailor accordingly especially regarding the clarity and simplicity of the language used. As the average literacy level in Stoke-on-Trent is that of a 10-11 year-old, all materials written for the public should reflect this and be pitched at this level.
- Ensure that Service Users are treated with dignity and respect.
- Abide by the Caldicott principles, Data Protection Act 1998 and any later version of this legislation, the General Data Protection Regulation (GDPR) and Freedom of Information Act 2000 in the handling and security of information, ensuring that it is kept accurate, up to date and kept only for as long as needed for the specified purpose.
- Ensure that any data management IT equipment used e.g. PC's, Laptops and Tablets is encrypted to the suitable level of security that ensures data is protected in the event of loss or theft. The standard encryption level accepted by the Authority is FIPS 140-2. The Authority will consider other encryption standards.
- Have in place a complaints policy (including a system to log complaints), and submit copies of formal complaints to the Authority within 10 Business Days.
- Have in place a system to log compliments.
- Have in place a serious untoward incident policy which includes ensuring that the Authority is alerted to any incidents related to the delivery of this service specification
- Promote equality of opportunity regardless of age, disability, gender, sexual orientation, race or religion in accordance with the requirement of the Equality Act 2010.
- Provisions are in place to ensure that the Provider adheres to any changes in legislation, NICE guidance or recommendations from appropriate regulatory or supervisory bodies.

- Has in place arrangements for monitoring quality and continuously improving levels of service delivery.
- Ensure at the Expiry Date that existing assets, resources (including any marketing/branding that has been developed) or equipment that has been previously transferred to, or purchased by the current provider in order to deliver the services listed in this Contract are either returned to the Authority or transferred to any new provider to enable continuity of service provision.. Access rights to IT systems and databases used to provide this service should revert to the Authority On the expiry or termination of this Contract or termination of any service under this Contract the Provider must co-operate fully with the Authority at the Provider's own cost to migrate the services in an orderly and timely manner to any successor provider.

## Security (data protection and Service User confidentiality and consent)

### Confidentiality and Service User Contract

The Service User will enter into a contract with the Pharmacist supplying the Champix. This will be agreed at the initial consultation and then recorded on PharmOutcome (data management system commissioned by Stoke-on-Trent City Council). The contract will ensure that the Service User understands how their data will be used and stored in accordance with data protection and GDPR. A copy of the contract is available within the PGD. This will be embedded into PharmOutcomes for the Pharmacist to use at the time of the appointment. Treatment should not proceed if the Service User does not sign the contract.

Under the GDPR the Pharmacist will be legally responsible for the following:

- Taking appropriate measures to ensure the security of processing of data
- Reporting of data breaches which infringe the GDPR or other data protection law
- Deleting or returning data at the end of the contract
- Recording of activity to allow the Authority as the data controller to comply with obligations
- Only act on the written instructions of the controller

The Pharmacist must:

- Ensure that staff processing the data are subject to a duty of confidence
- Assist the controller in providing access to any data and allowing Service Users to exercise their rights under GDPR
- Assist the controller in meeting its GDPR obligations in relation to the security of processing, the notification of personal data breaches and data protection impact assessments. Delete or return all personal data to the controller as requested at the end of the contract.

All data and information should be handled and stored in accordance with the Data Protection Act 1998 and any later version of this legislation, the General Data Protection Regulation (GDPR) and the Freedom of Information Act 2000 in the handling and security of

information, ensuring that it is kept accurate, up to date and kept only for as long as needed for the specified purpose.

## Implementation Timetable

The supply of Varenicline, via the PGD and within this contract, will commence on 1 January 2019

To become an accredited Pharmacist and start issuing Varenicline Pharmacists will need to have completed the self-accreditation process and signed the PGD and attended the face to face training. This includes Pharmacists which are already supplying Champix under the previous contract and PGD.

In addition the accredited Pharmacist must be employed or contracted/working at the time in an accredited Pharmacy (an accredited Pharmacy is one which has signed the contract to deliver this work).

## Payment

### Service Charge

Pharmacists will be paid monthly in arrears as follows

Consultation (per Service User)	Payment
First Consultation	£15
Subsequent Consultations	£2.50

### Payment for Medication

The Pharmacist will be reimbursed for the cost of Varenicline that is purchased and supplied to Service Users accessing the stop smoking service. This will be paid monthly, in arrears. The Pharmacist will be required to input the medication details onto PharmOutcomes in order to make a claim which will be subject to the correct completion of fields and invoice.

Prescription charges will be collected where applicable. Where clients are exempt from prescription charges Pharmacists will need to ask clients if they have evidence to support their claim and record this on PharmOutcomes.

## Appendix 1-Varenicline Patient Group Direction

Patient Group  
Direction (PGD) for  
the supply of  
Varenicline  
(Champix®) Via  
Accredited  
Pharmacists  
Authorised by Stoke  
on Trent City Council

## Document Control

Document Control	
Document name	Patient Group Direction (PGD) for the supply of Varenicline (Champix®)
Date authorised	
Valid from	1 January 2019
Planned review dates	31 December 2020
End Date	30 September 2021

Date	Who	Change	Version
26/1/2015	Katty Ager	Created	Version 1
30/7/2015	Rochelle Edwards	New letters-appendix 4 Incident reporting form-appendix 7	Version 1
07/10/2015	Rochelle Edwards	Appendix 3 and 4 amended	Version 1
03/11/2015	Rochelle Edwards	Miscellaneous Changes	Version 1
16/11/2015	Mani Hussain	Section 3.6	Version 1
28/6/2016	Rochelle Edwards	Removal of black triangle status and updates from EAGLES trial as per Summary of Product Characteristics (SPC)	Version 2
23/10/2018	PGD Working Group	Inclusion of General Data Protection Regulations (GDPR) Updates from SPC Removal of pro-forma for initial and subsequent supplies of Varenicline (originally Appendix 2 and 4)	Version 3

## Overview

- It is the responsibility of the professional working under this PGD to verify that the Service User fulfils the stated criteria for supply of the treatment concerned.
- It is not appropriate to have a PGD in place that is infrequently used by health care professionals because of progressive unfamiliarity with its contents. Any healthcare professional that works to a PGD infrequently should consider whether to cease doing so.

- Varenicline is a licensed Prescription Only Medicine (POM) as defined by the Medicines Act 1968 and Prescription Only Medicines (Human Use) Order 1997.
- Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
- The black triangle and associated warnings have been removed as a result of the EAGLES2 trial which is the largest comparative randomised controlled trial of approved stop smoking medication.
- Clinical indications, Contraindications, and Cautions are as set out in the Summary of Product Characteristics.
- Inclusion and Exclusion criteria are summarised within the PGD.
- "Off Label" use is not supported by the PGD.

### Supporting Documentation

- NICE technology appraisal guidance 123, Varenicline for smoking cessation. <https://www.nice.org.uk/guidance/ta123/resources/guidance-varenicline-for-smoking-cessation-pdf>
- NICE public health guidance 10, Smoking cessation services. <https://www.nice.org.uk/guidance/ph10/resources/guidance-smoking-cessation-services-pdf>
- NCSCT, Local Stop Smoking Services, Service and Delivery Guidance 2014. [http://www.ncsct.co.uk/usr/pub/LSSS\\_service\\_delivery\\_guidance.pdf](http://www.ncsct.co.uk/usr/pub/LSSS_service_delivery_guidance.pdf)
- NCSCT, Varenicline: effectiveness and safety [http://www.ncsct.co.uk/usr/pub/Varenicline\\_effectiveness\\_safety.pdf](http://www.ncsct.co.uk/usr/pub/Varenicline_effectiveness_safety.pdf)
- UKMi, Medicines Q&A's, Which medicines need dose adjustment when a patient stops smoking? UKMi 136.
- Professor Robert M Anthenelli, Professor Neal L Benowitz, Professor Robert West, Lisa St Aubinm, Thomas McRae, David Lawrence, John Ascher, Cristina Russ, Alok Krishen, Professor A Eden Evins (2016) 'Neuropsychiatric safety and efficacy of varenicline, bupropion and nicotine patch in smokers with and without psychiatric disorders (EAGLES)', *The Lancet*, Volume 387, No.10037, p2507-2520.

### Professional Indemnity

The Pharmacist should be a full registered member of the General Pharmaceutical Council (GPhC) and must work within their professional code of ethics at all times. Membership of the Royal Pharmaceutical Society (RPS) is highly recommended. The Pharmacist must ensure their professional indemnity cover is provided by the National Pharmaceutical Association (NPA) or other organisation which has confirmed that this activity is included in their policy.

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<sup>2</sup> Professor Robert M Anthenelli, Professor Neal L Benowitz, Professor Robert West, Lisa St Aubinm, Thomas McRae, David Lawrence, John Ascher, Cristina Russ, Alok Krishen, Professor A Eden Evins (2016) 'Neuropsychiatric safety and efficacy of varenicline, bupropion and nicotine patch in smokers with and without psychiatric disorders (EAGLES)', *The Lancet*, Volume 387, No.10037, p2507-2520.

### **Clinical Governance**

The Pharmacist will have in place comprehensive and demonstrative system of clinical governance. The pharmacy will have in place a standard operating procedure (SOP) for the provision of this service.

### **Staff Characteristics and Training Requirements**

- Pharmacist registered with General Pharmaceutical Council.
- Pharmacists registered with the Centre for Pharmacy Postgraduate Education (CPPE).
- Working within a Stoke on Trent pharmacy where there is an agreement with Stoke-on-Trent County Council to supply Varenicline under a PGD.

The Pharmacist must be able to demonstrate that they have the necessary competencies to supply Varenicline under a PGD. Training for this service is self-accreditation. Pharmacists are expected to map their competencies to the Stop Smoking DoC and are expected to access any training they deem necessary in order to meet the competencies. In addition, all Pharmacists will need to read and complete the following;

- Read and complete the CPPE e-learning - Stop Smoking: very brief advice and its related assessments
- Read and complete the CPPE e-learning- Patient Group Directions and its related assessments
- Read and understand the PowerPoint Presentation agreed by the Authority (available on the LPC <https://www.northstaffslpc.co.uk/>)

There may still be ad hoc face to face sessions which Pharmacists are encouraged to attend to ensure continued professional development.

This PGD will only apply whilst the Pharmacist is employed or contracted/working at the time in an accredited Pharmacy.

Accredited Pharmacies will have a suitable private consultation room / area which meet the same criteria as that required to provide Advanced Pharmaceutical Services and has been approved by NHSE and is available for all Service User consultations.

The Pharmacist should be aware of any change to the recommendations for the medicine listed. It is the professional responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of individual scope of practice.

### **Reimbursement and Prescription Charges**

Pharmacists will be paid £15 for the first supply of Varenicline and £2.50 for subsequent supplies. The data will be collected on PharmOutcomes, a data management system commissioned by the Authority.

Prescription charges will be collected where applicable. Where Service Users are exempt from prescription charges Pharmacists will need to ask Service Users if they have evidence to support their exemption status.

<b>1. Reason for introducing PGD</b>		
<p>For accredited Pharmacists to supply Varenicline within its licensed indications as an option for smokers who have expressed a desire to quit smoking. Service Users can be supplied Varenicline via an accredited Pharmacist if:</p> <ul style="list-style-type: none"> <li>• The Pharmacist is accredited by Stoke-on-Trent City Council to provide stop smoking support (this includes subcontracted Pharmacists).</li> <li>• If a Service User is accessing a stop smoking service accredited by Stoke-on-Trent City Council for behavioral support and wishes to use Varenicline to aid their quit attempt</li> </ul>		
<b>2. Clinical Condition or situation to which this PGD applies</b>		
2.1	Define condition/situation	Varenicline as an option for Service Users wishing to quit smoking whilst receiving behavioural support from an Accredited Stop Smoking Provider.
2.2	Criteria for inclusion ALL MUST APPLY	<ul style="list-style-type: none"> <li>• Service Users who have set a target quit date with an Accredited Stop Smoking Provider.</li> <li>• Service Users aged 18 years of age and over.</li> <li>• Tobacco users identified as sufficiently motivated to quit.</li> <li>• Tobacco users who are receiving support to stop smoking with a Stoke-on-Trent accredited Stop Smoking Service and who have a Varenicline initial referral letter Appendix 1a and Appendix 1b for subsequent supplies.</li> <li>• A medical history is taken and documented to establish that there are no contraindications for treatment with Varenicline and that any cautions for use are recorded (see Criteria for exclusion and Criteria for cautions). PharmOutcomes will display a proforma for the Initial Supply of Varenicline and a proforma for Subsequent Supplies of Varenicline which will need to be completed.</li> <li>• Service User consent has been obtained and recorded.</li> </ul>
2.3	Criteria for exclusion	<ul style="list-style-type: none"> <li>• Tobacco users not sufficiently motivated to quit or use Varenicline.</li> <li>• Service User's under 18 years of age.</li> <li>• Sensitivity to Varenicline or any of its excipients including Service Users who have had a serious allergic or skin reaction from a previous course of Varenicline.</li> <li>• Pregnancy/ Breastfeeding.</li> <li>• Service User's already receiving Varenicline prescribed</li> </ul>

		<p>by GP (unless an agreed transfer of care has taken place).</p> <ul style="list-style-type: none"> <li>• Service User's already using other smoking cessation pharmacotherapies.</li> <li>• Patient with history of renal impairment or end stage renal disease as decreased clearance by kidney increases side effects.</li> <li>• Service User's with history of epilepsy or history of fits or seizures.</li> <li>• Substance misuse patients.</li> <li>• Service Users who have experienced serious or significant side effects from a previous course of Varenicline.</li> <li>• Service User's with active psychiatric illness. Service Users who have received medical treatment for a psychiatric illness in the past 12 months. <i>The EAGLES<sup>3</sup> study showed that Champix was not associated with an increased risk of Neuropsychiatric safety (NPS) adverse events vs placebo in smokers with or without a history of psychiatric disorder.</i></li> <li>• Service Users who have schizophrenia or schizoaffective disorder.</li> <li>• Service Users who are planning to use an electronic nicotine delivery device (ENDS) as part of their quit attempt.</li> </ul> <p>Please see section 2.6 for action when a Service User is excluded.</p>
2.4	Special warnings and precautions for use [to include consideration of concurrent medication]	<p><b>Effect of smoking cessation</b></p> <p>Physiological changes resulting from smoking cessation with or without treatment with Varenicline, may alter the pharmacokinetics or pharmacodynamics of some medicinal products for which dose adjustment may be necessary. Examples include</p> <ul style="list-style-type: none"> <li>• Theophylline</li> <li>• Warfarin</li> <li>• Insulin.</li> </ul> <p>As smoking induces CYP1A2 smoking cessation may result in an increase of plasma levels of CYP1A2 substrates.</p>

<sup>3</sup> Professor Robert M Anthenelli, Professor Neal L Benowitz, Professor Robert West, Lisa St Aubinm, Thomas McRae, David Lawrence, John Ascher, Cristina Russ, Alok Krishen, Professor A Eden Evins (2016) 'Neuropsychiatric safety and efficacy of varenicline, bupropion and nicotine patch in smokers with and without psychiatric disorders (EAGLES)', *The Lancet*, Volume 387, No.10037, p2507-2520.

		<p><b><u>Drug Interactions</u></b> No clinically 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 dose adjustment is not required.</p> <p><b><u>Neuropsychiatric symptoms</u></b> Pharmacists should be aware of the possible emergence of serious neuropsychiatric symptoms in Service Users attempting to quit smoking with or without treatment. If serious neuropsychiatric symptoms occur whilst on Varenicline treatment, patients should discontinue Varenicline immediately and contact the Pharmacist for re-evaluation of treatment.</p> <p><b><u>History of Psychiatric Disorders</u></b> Smoking cessation, with or without pharmacotherapy, has been associated with exacerbation of underlying psychiatric illness (eg depression). Care should be taken with Service Users with a history of psychiatric illness and Service Users should be advised accordingly.</p> <p><b><u>Cardiovascular Events</u></b> Service Users taking Varenicline should be instructed to notify the Pharmacist of new or worsening cardiovascular symptoms and to seek immediate medical attention if they experience signs and symptoms of myocardial infarction or stroke.</p> <p><b><u>Hypersensitivity Reactions</u></b> There have been post-marketing reports of hypersensitivity reactions including angioedema in Service Users treated with Varenicline, clinical signs included swelling of the face, mouth (tongue, lips and gums) neck (throat and larynx) and extremities. There were rare reports of life threatening angioedema requiring urgent medical attention due to respiratory compromise. Service Users experiencing these symptoms should discontinue treatment with Varenicline and contact the Pharmacist immediately.</p> <p><b><u>Cutaneous Reactions</u></b> There have been post-marketing reports of rare but severe cutaneous reactions, including Stevens-Jonson Syndrome and Erythema Multiforme in Service Users</p>
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		<p>using Varenicline. As these skin reactions can be life threatening, Service Users should discontinue treatment at the first sign of rash or skin reaction and contact the Pharmacist immediately. <b>Note:</b> Service Users who have had a serious allergic or skin reaction from a previous course of Varenicline are excluded.</p> <p><b><u>Treatment Discontinuation</u></b>  At the end of treatment discontinuation of Varnenicline was associated with an increase in irritability, urge to smoke, depression, and/or insomnia in up to 3% of patients. The Pharmacist should inform the Service User accordingly and discuss or consider the need for dose tapering.</p> <p><b><u>GP Notification</u></b>  The Service Users GP will be notified of every initial supply of Varenicline within 2 working days (see Appendix 2 for exemplar information) this will be done via PharmOutcomes using secure nhs.net accounts when the Service Users data is saved on PharmOutcomes. On the rare occasion where no nhs.net account is available to PharmOutcomes the Pharmacists will be informed by the system and must make alternative arrangements to send the information (within 2 working days).</p> <p>In addition, if a Service User is a diabetic or is taking theophylline/aminophylline or warfarin, the letter provided in Appendix 3 must be completed and given to the Service User to take to their GP or relevant clinic to notify them of their quit attempt/use of Varenicline</p> <p>For further information please refer to <a href="#">UKMi</a> "Which medicines need dose adjustment when a patient stops smoking?" UKMi Q&amp;A 136.4</p>
2.5	Security (data protection and Service User Confidentiality Contract)	<p>The Service User will enter into a contract with the Pharmacist supplying the Champix. This will be agreed at the initial consultation and then recorded on PharmOutcome (data management system commissioned by Stoke-on-Trent City Council). The contract will ensure that the Service User understands how their data will be used and stored in accordance with data protection and GDPR. A copy of the contract is available in Appendix 4. This will be embedded into PharmOutcomes for the Pharmacist to use at the time of the appointment. Treatment should not proceed if the Service User does not</p>

		<p>sign the contract.</p> <p>Under the GDPR the Pharmacist will be legally responsible for the following:</p> <ul style="list-style-type: none"> <li>• Taking appropriate measures to ensure the security of processing of data</li> <li>• Reporting of data breaches which infringe the GDPR or other data protection law</li> <li>• Deleting or returning data at the end of the contract</li> <li>• Recording of activity to allow the Authority as the data controller to comply with obligations</li> <li>• Only act on the written instructions of the controller</li> </ul> <p>The Pharmacist must:</p> <ul style="list-style-type: none"> <li>• Ensure that staff processing the data are subject to a duty of confidence</li> <li>• Assist the controller in providing access to any data and allowing Service Users to exercise their rights under GDPR</li> <li>• Assist the controller in meeting its GDPR obligations in relation to the security of processing, the notification of personal data breaches and data protection impact assessments</li> <li>• Delete or return all personal data to the controller as requested at the end of the contract.</li> </ul> <p>All data and information should be handled and stored in accordance with the Data Protection Act 1998 and any later version of this legislation, the General Data Protection Regulation (GDPR) and the Freedom of Information Act 2000 in the handling and security of information, ensuring that it is kept accurate, up to date and kept only for as long as needed for the specified purpose.</p>
2.6	Action if Service User excluded	If the GP has informed the Pharmacist that the Service User should not receive the medication, as a result of the email notification or letter (described in section 2.4) then

		<p>the Pharmacist should use the letter in Appendix 5 to inform the Service User.</p> <p>Pharmacists which are also Accredited Stop Smoking Providers should offer Service Users the option of NRT. Where a Service User has been referred by an Accredited Stop Smoking Service they should be referred back to the service. Pharmacists should notify the Accredited Stop Smoking Provider by telephone (this will be on each referral letter) within 2 working days with an explanation as to why the Service User was excluded. This should be recorded onto PharmOutcomes.</p> <p>Document action in patient medication record (PMR).</p>
2.7	Action if treatment declined by Service User	<p>Pharmacists providing Stop Smoking Services should offer other available smoking cessation options if appropriate. Where a Service User has been referred by an Accredited Stop Smoking Service they should be referred back to the service. Pharmacists should notify the Accredited Stop Smoking Provider by telephone within 2 working days with an explanation as to why the treatment was declined. This should be recorded onto PharmOutcomes. Document action in patient medication record (PMR).</p>
2.8	Action if Pharmacist is unavailable to supply subsequent supplies of Varenicline	<p>After the initial supply of Varenicline the Service User should normally receive subsequent supplies from the same Pharmacy by an accredited Pharmacist. If this is not possible for example due to sickness absence then the Service User can attend another participating Pharmacy. In this situation the new Pharmacist will need to re-assess the suitability for Varenicline. The Pharmacist will be reimbursed at the initial supply price of £15 to reflect this work.</p>
<b>3. Description of treatment.</b>		
3.1	Generic name of medicine and form (e.g. tablets)	<p>Varenicline (Champix®) 0.5mg film coated tablets</p> <p>Varenicline (Champix®) 1mg film coated tablets</p>
3.2	Legal status POM/P/GSL	Prescription Only Medicine – subject to intensive monitoring requirements
	Licensed or unlicensed use [If unlicensed state rationale for use]	Licensed
3.3	Precautions, facilities & supplies	<p>Store in a cool dry place below 30 degrees Celsius.</p> <p>Order supplies from licensed pharmacy wholesalers.</p>
3.4	Dose and Frequency	<b>In all circumstances dosing should follow the recommendations in the Varenicline Summary of Product Characteristics <a href="http://www.medicines.org.uk/emc">http://www.medicines.org.uk/emc</a></b>

		<p><b>Days 1 – 3:</b> 0.5 mg (white tablets) once daily</p> <p><b>Days 4 – 7:</b> 0.5 mg(white tablets) twice daily</p> <p><b>Week 2 to week 12:</b> 1 mg (light blue tablets) twice daily Patients who cannot tolerate the adverse effects of Varenicline can have the dose lowered temporarily or permanently to 0.5mg (white tablet) twice daily. (See BNF 4.10.2)</p> <p><b>Extending course to reduce risk of relapse:</b> The normal 12-week course can be repeated in abstinent individuals to reduce risk of relapse. Approval must be sought from the Authority for extending the treatment course beyond 12weeks. Approval will then trigger the additional information to become available on PharmOutcomes and enable the relevant data to be captured.</p> <p><b>Dose tapering</b> In patients with a high risk of relapse, dose tapering may be considered at the end of the standard 12 weeks of treatment.</p> <p><b>Quit date</b> All Service Users must have set a target quit date before the commence treatment. Treatment should be started 1-2 weeks before the actual quit date.</p>
3.5	Route / method of administration	Oral
3.6	Total dose and number of times treatment can be administered; state time frame	<ul style="list-style-type: none"> <li>• Service Users should be initially supplied a 14 day initiation pack and should have set a target quit date 7 to 14 days after initiation</li> <li>• Subsequent supplies using the 14-day prescription packs, complete with Patient Information leaflet, should be provided throughout the quit attempt.</li> <li>• The normal treatment course is 12 weeks</li> <li>• An additional course of 12 weeks treatment of Varenicline at either 0.5mg or 1 mg twice daily (depending on previous dose) may be considered with</li> </ul>

		<p>permission from commissioner</p> <ul style="list-style-type: none"> <li>The maximum length of treatment is 24 weeks. All supplies of Varenicline must be labelled in line with the labelling requirements for a <i>dispensed medicine</i> as stated within Schedule 5 of The Medicines (Marketing Authorisations Etc) Regulations 1994, No 3144 as amended.</li> <li>In addition to the above, the label must also state the words "Supplied under a PGD" to help with audit purposes.</li> </ul>
3.7	Instructions on identifying, managing & reporting adverse drug reactions	<p>For Service Users experiencing <b>mild</b> adverse effects after dose increase to 1mg twice daily, consider a temporary or permanent dose lowering to 0.5 mg twice daily. (See BNF 4.10.2) Review at next scheduled appointment.</p> <p><b>Very Common and Common Adverse Reactions of Varenicline</b></p> <ul style="list-style-type: none"> <li>Infections and infestations <ul style="list-style-type: none"> <li>Very common-Nasopharyngitis</li> <li>Common-bronchitis, sinusitis</li> </ul> </li> <li>Metabolism and nutrition disorders <ul style="list-style-type: none"> <li>Common-weight increased, decreased appetite, increased appetite</li> </ul> </li> <li>Psychiatric Disorders <ul style="list-style-type: none"> <li>Very Common-abnormal dreams, insomnia</li> </ul> </li> <li>Nervous System Disorders <ul style="list-style-type: none"> <li>Very Common-headaches</li> <li>Common-somnolence, dizziness, dysgeusia</li> </ul> </li> <li>Respiratory, thoracic and mediastinal disorders <ul style="list-style-type: none"> <li>Common-Dyspnea, cough</li> </ul> </li> <li>Gastrointestinal disorders <ul style="list-style-type: none"> <li>Very Common-Nausea</li> </ul> </li> </ul>

		<p>Common-Gastroesophageal reflux disease, vomiting constipation, diarrhoea, abdominal distension, abdominal pain, toothache, dyspepsia, flatulence, dry mouth</p> <ul style="list-style-type: none"> <li>• Skin and subcutaneous tissue disorders</li> </ul> <p>Common-rash, pruritus</p> <ul style="list-style-type: none"> <li>• Musculoskeletal and connective tissue disorders</li> </ul> <p>Common-Arthralgia, myalgia, back pain</p> <ul style="list-style-type: none"> <li>• General Disorders and administration site conditions</li> </ul> <p>Common-chest pain and fatigue</p> <ul style="list-style-type: none"> <li>• Investigations</li> </ul> <p>Common-liver function test abnormal</p> <p><b>For comprehensive information please consult the Summary of Product Characteristics which can be found at <a href="https://www.medicines.org.uk/emc/medicine/19045">https://www.medicines.org.uk/emc/medicine/19045</a></b></p> <p><b>Symptoms of Stopping Smoking</b></p> <p>Smoking cessation with or without treatment is associated with various symptoms. For example, dysphoric or depressed mood; insomnia, irritability, frustration or anger; anxiety; difficulty concentrating; restlessness; decreased heart rate; increased appetite or weight gain have been reported in Service Users attempting to stop smoking. No attempt has been made in either the design or the analysis of the studies to distinguish between adverse events associated with study drug treatment or those possibly associated with nicotine withdrawal.</p> <p>Service Users should be asked at every appointment about their mood and the answer recorded on PharmOutcomes. If the Service User develops suicidal thoughts or behaviour they should be told to stop treatment and contact their GP immediately. Where the pharmacy is not the Service User's Stop Smoking Service Provider, the Pharmacist should also inform the Accredited Stop Smoking Provider. This should also be recorded on PharmOutcomes. If the Service User, family or care givers have concerns about agitation, depressed mood or changes in behaviour Varenicline should be stopped immediately.</p>
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		<p>Please refer to current BNF and SPC for full details.</p> <p><b>The Pharmacist is required to report all adverse reactions to the Medicine and Health Products Regulatory Agency (MHRA) using the Yellow Card Scheme. It is possible to do so online at: <a href="http://www.mhra.gov.uk/yellowcard">www.mhra.gov.uk/yellowcard</a></b></p> <p><b>Any adverse reactions should be reported to the GP. A copy of the information reported using the yellow card system should also be emailed to the Authority using the following email address <a href="mailto:stopsmoking@stoke.gov.uk">stopsmoking@stoke.gov.uk</a> . This should only be anonymised data to comply with Information Governance requirements.</b></p>
3.8	Written/verbal advice for Service User before/after treatment and management	<ul style="list-style-type: none"> <li>• Service Users should be advised to set a quit date 7 to 14 days after initiation</li> <li>• The major reasons for Varenicline failure are: <ul style="list-style-type: none"> <li>- Unrealistic expectations</li> <li>- Lack of preparation for the fact that the tablets may cause nausea</li> <li>- Insufficient or incorrect use</li> </ul> </li> <li>• It is important to make sure that the Service User understands the following points: <ol style="list-style-type: none"> <li>1. Varenicline is not a magic cure - effort and determination are crucial</li> <li>2. It works by acting on the parts of the brain which are affected by nicotine in cigarettes</li> <li>3. It does not remove all temptation to smoke, but it does make abstinence easier ('it takes the edge off the discomfort')</li> <li>4. Varenicline is safe, but about a third of Service Users may experience mild nausea some 30 minutes after taking it. This reaction usually diminishes gradually over the first few weeks, and most Service Users tolerate it without problems. If Service User is unable to tolerate due to nausea consider reducing the dose to 0.5mg or refer back to the Stop Smoking Provider.</li> <li>5. Instruct on correct use and daily dose. Use mock product packaging for the explanation. Service Users should take Varenicline for 7 to 14 days before stopping smoking.</li> </ol> </li> <li>• For patients who have successfully stopped smoking at</li> </ul>

		<p>the end of 12 weeks, an additional course of 12 weeks treatment with Varenicline at the current dose (0.5mg or 1 mg) twice daily may be considered for maintenance of abstinence in exceptional cases with permission from the commissioner.</p> <ul style="list-style-type: none"> <li>• At the end of treatment, discontinuation of Varenicline has been associated with an increase in irritability, urge to smoke, depression, and/or insomnia in up to 3% of Service Users. The Pharmacist should inform the Service User accordingly and discuss or consider the need for dose tapering.</li> <li>• No clinically significant 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 dose adjustment is not required.</li> </ul> <p><b><u>Alcohol</u></b></p> <p>Service Users should decrease the amount of alcohol they drink while taking Varenicline until they know if it affects their ability to tolerate alcohol. Some people experienced increased drunkenness, unusual or sometimes aggressive behaviour, or memory loss of events while consuming alcohol during treatment with Varenicline.</p> <p><b><u>Effects on ability to drive and use machines</u></b></p> <p>Varenicline may have minor or moderate influence on the ability to drive and use machines. It may cause dizziness, somnolence and transient loss of consciousness and therefore may influence the ability to drive and use machines. Service Users are advised not to drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether this medicinal product affects their ability to perform these activities.</p>
3.9	Communication with Service User's General Practice	In every case when the initial supply of Varenicline is made in accordance with this PGD, the Pharmacist must inform the Service User's General Practitioner of the supply within two working days. This will be done through

		<p>secure nhs.net email accounts via PharmOutcomes using secure nhs.net accounts when the Service User's data is saved on PharmOutcomes. On the rare occasion where no nhs.net account is available to PharmOutcomes the Pharmacists will be informed by the system and must make alternative arrangements to send the information (within 2 working days). (See Appendix 2 for an exemplar of the information which will be sent).</p> <p>As per section 2.4 where a dose adjustment of current medication is required the Service User should be advised to contact their GP or appropriate clinic to discuss (use Appendix 3).</p>
3.10	Communication with Service User's Stop Smoking Service Provider	Where the pharmacy is not the Service User's Stop Smoking Service Provider, the Pharmacist should inform the Service Provider the reasons for not supplying or when the Service User fails to attend an appointment Pharmacists should notify the Accredited Stop Smoking Provider by telephone within 2 working days, with an explanation as to why Varenicline wasn't supplied. This action should also be recorded onto PharmOutcomes.
3.11	Arrangements for referral for medical advice	Pharmacists must be able to advise Service User/parent/carer or family member what action to take in the event of the Service User developing any clinically significant symptoms from stopping smoking or side effects from the medication and the most appropriate action (e.g. dose reduction or medical service to contact).
3.12	Information on follow-up management	Advise to seek urgent medical advice if a severe reaction to the medication occurs.
3.13	Method of recording and records management	<p>Pharmacists should note the following when receiving referral and subsequent supply letters</p> <ul style="list-style-type: none"> <li>• Only original letters should be accepted.</li> <li>• An appointment should have been made with the Pharmacist prior to attending.</li> <li>• The letter is only valid for one month from the date of issue. If a letter is received after this then the Pharmacist should check with the Accredited Stop Smoking Provider that the Service User is still attending for behavioural support.</li> <li>• PharmOutcomes should be used to ensure the Service User has not already attended an appointment with a</li> </ul>

		<p>Pharmacist for a supply of Varenicline (using unique supply reference code)</p> <ul style="list-style-type: none"> <li>• The letter should be retained, in accordance with the Data Protection Act 1998 and General Data Protection Regulations, for audit purposes.</li> </ul> <p>A number of fields will need to be completed on PharmOutcomes in order for payment to be processed, these include:</p> <ul style="list-style-type: none"> <li>• Service User's name, address, date of birth and GP details.</li> <li>• The accredited Provider who referred and the Advisor</li> <li>• Date supplied and name of the Pharmacist who supplied the medication.</li> <li>• Batch number and expiry date.</li> <li>• Reason for inclusion.</li> <li>• Advice given to Service User.</li> <li>• Whether the Service User is entitled to free prescription charges and if so whether evidence has been seen.</li> <li>• Completion of contract in line with GDPR requirements.</li> </ul> <p>Inputting of data should be done with 48 hours following the appointment with the Service User.  Details of any adverse drug reaction and actions taken including documentation in the Service User's medical record via GP (as well as reporting to the MHRA using the 'Yellow Card' reporting system). Any paper records will need to be stored in accordance with Data Protection Act 1998 and any later versions of this legislation, GDPR and the Freedom of Information Act 2000.</p>
<b>4. Acknowledgements</b>		
This Varenicline PGD has been adapted, with permission, from Worcestershire Public Health Department part of Worcestershire County Council.		
<b>5. Audit</b>		
This PGD will be monitored by the Local Authority in accordance with local and national		

requirements for PGDs. Pharmacists accredited to supply Varenicline must also regularly audit the service they are providing to ensure that the quality standards are being met.

## 6. Management

6.1	PGD Group	Andy Pickard, Pharmacy Advisor - NHS England North Midlands Staffordshire and Shropshire  Dr Gill Hall, Service Development Officer - South Staffordshire LPC  Tania Cork, Chief Officer - North Staffs and Stoke Local Pharmaceutical Committee  Rochelle Edwards, Senior Health Improvement Specialist - Stoke-on-Trent City Council		
6.2	Authorisation This PGD has been approved by:			
	<b>Name and Designation</b>	<b>Organisation</b>	<b>Signature</b>	<b>Date</b>
	Dr Paul Edmondson-Jones, Director of Adult Social Care, Health Integration and Wellbeing (Lead Doctor)	Stoke-on-Trent City Council		
	Dr Manir Hussain, Deputy Director of Primary Care and Medicines Optimisation (Lead Pharmacist)	Stoke-on-Trent Clinical Commissioning Group		24/10/18
	Gerry Clarke- Assistant Director Governance	Stoke-on-Trent City Council		
	Rochelle Edwards, Senior Health Improvement Specialist (Lead Commissioner)	Stoke-on-Trent City Council		

**Patient Group Direction (PGD) for administration of Varenicline tablets  
by Pharmacists accredited by Stoke-on-Trent City Council**

This PGD is effective from 1 January 2019 to 30 September 2021. By completing the information in the table below the Pharmacist is agreeing to the following:

- I have read and understood the PGD and will work within its scope.
- I confirm that I will maintain my Declaration of Competence.
- I agree to maintain my clinical knowledge appropriate to my practice.
- I confirm my indemnity insurance covers my scope of practice.

<b>Name</b>	
<b>Position</b>	
<b>Signature</b>	
<b>Date</b>	

## Initial Referral Letter for Varenicline

Stop Smoking Advisor to complete the following

<b>Service User Name</b>	
<b>Service User Quit Manager ID Number</b>	
<b>Unique Supply Number-made up of the following: 2 letter initials QM ID supply number</b>	
<b>GP Practice</b>	
<b>Stop Smoking Provider</b>	
<b>Signature of Stop Smoking Advisor</b>	
<b>Print Name</b>	
<b>Date</b>	

Please ensure **all** above are completed before you give to Service User

Dear Pharmacist

The above Service User is attending stop smoking support and has expressed an interest in using Varenicline as an aid to quitting smoking. As an approved Pharmacist who can supply Varenicline under the Stoke on Trent PGD please can you assess the Service User for clinical suitability and supply the initiation pack if appropriate. The Service User has set a quit date and agreed to attend the Stop Smoking Service for regular behavioural support and understands that the decision to supply will be made following your full assessment. If you require any further information please contact the Stop Smoking Service Provider on \_\_\_\_\_.

Kind Regards

**Notes to Pharmacist**

Only original letters should be accepted.

An appointment should have been made with the Pharmacist prior to attending.

The letter is only valid for one month from the date of the letter. If a letter is received after this then the Pharmacist should check with the Accredited Stop Smoking Provider that the Service User is still attending for behavioural support.

Please use PharmOutcomes to ensure the Service User has not already attended an appointment with a Pharmacist for a supply of **Varenicline** (using unique supply reference code).

Please retain this letter, in accordance with the Data Protection Act, 1998 and any later version of this legislation, the General Data Protection Regulation (GDPR) and the Freedom of Information Act 2000 in the handling and security of information, ensuring that it is kept accurate, up to date and kept only for as long as needed for the specified purpose.

## **Appendix 1b**

## Referral Letter for subsequent supplies of Varenicline

Stop Smoking Advisor to complete the following

<b>Service User Name</b>	
<b>Service User Quit Manager ID Number</b>	
<b>Unique Supply Number-made up of the following: 2 letter initials QM ID supply number</b>	
<b>GP Practice</b>	
<b>Stop Smoking Provider</b>	
<b>Signature of Stop Smoking Advisor</b>	
<b>Print Name</b>	
<b>Date</b>	

Please ensure **all** above are completed before you give to Service User

Dear Pharmacist

Please could you reassess the above Service User and supply the next instalment of Varenicline. The Service User is continuing to attend the Stop Smoking Service for regular behavioural support and is maintaining their quit smoking status. The Service User understands that continued supply of Varenicline is reliant on your assessment to ensure that the medicine continues to be safe and effective.

If you require any further information please contact the Stop Smoking Service Provider on

\_\_\_\_\_.

Kind Regards

### **Notes to Pharmacist**

Only original letters should be accepted.

An appointment should have been made with the Pharmacist prior to attending.

The letter is only valid for one month from the date of the letter. If a letter is received after this then the Pharmacist should check with the Accredited Stop Smoking Provider that the Service User is still attending for behavioural support.

Please use PharmOutcomes to ensure the Service User has not already attended an appointment with a Pharmacist for a supply of **Varenicline** (using unique supply reference code)

Please retain this letter, in accordance with the Data Protection Act, 1998 and any later version of this legislation, the General Data Protection Regulation (GDPR) and the Freedom of Information Act 2000 in the handling and security of information, ensuring that it is kept accurate, up to date and kept only for as long as needed for the specified purpose.

**Appendix 2 Exemplar of information sent to GP**



**Pharmacist Notification to GP of supply of Varenicline will be emailed to the Service Users GP via PharmOutcomes using secure NHS email account when the patient data is saved on PharmOutcomes . Where an nhs.net email is not available to PharmOutcomes the Pharmacist will be informed by the system and must make alternative arrangements, to send the information (within 2 working days).**

**URGENT & CONFIDENTIAL**

Data protection confidentiality note: This message is intended only for the use of the individual or entity to whom it is addressed and may contain information that is privileged, confidential and exempt from disclosure under law. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited.

- GP Name
- GP Address
- Patient Name
- Address
- DOB
- Telephone

**Dear Doctor**

I am contacting you to advise you that your patient has expressed a wish to use Varenicline as an aid to stopping smoking, and a medical history has taken place to assess whether it is appropriate for them to receive it. Please note the following:

	I have ascertained that your Patient does not have any contraindications, or risk factors, for taking Varenicline and meets the criteria for a supply to be made under the local Patient Group Direction. If you have any concerns about this person commencing Varenicline then please do not hesitate to contact me.
	Your patient is (delete as appropriate) diabetic / taking theophylline / aminophylline / warfarin therefore physiological changes associated with stopping smoking may necessitate a dose adjustment of their current medication.
Your patient has been advised to visit their GP if symptoms of toxicity start. Your patient has agreed to regularly attend the Stop Smoking Service for behavioural support which will increase their chance of quitting smoking successfully.	

Pharmacy Address:

Pharmacist name and contact number:

Date:

**Appendix 3**



**Pharmacist supply of Varenicline**

Service User Name \_\_\_\_\_

GP Practice \_\_\_\_\_

**Service User Action Needed** (Pharmacist to tick all that apply):

Please let your GP know that you are taking Varenicline if you visit them during your 12 week course.	✓
Because you take aminophylline or theophylline for your breathing it is important to contact your GP practice to make an appointment to talk about your dose. This is because when you stop smoking it changes how much theophylline or aminophylline you need. (Remember - stopping smoking is the healthy option but you do need to speak to your GP/Prescriber to adjust your dose).	
Because when you take warfarin stopping smoking can affect your blood levels. Please advise the clinic that you are quitting using Varenicline. If you are not due to have a blood test before you start this medication it would be a good idea to ring the clinic to let them know (you may be asked to come in for an earlier blood test to keep INR levels correct)	
Because you use insulin you are advised to monitor your blood glucose levels closely. If you have any concerns about your levels please talk to your diabetic nurse/GP/Prescriber.	

Pharmacist signature:

Pharmacy Stamp

Pharmacist name and contact number:

## Appendix-4

### SUPPORTING YOU TO BECOME SMOKEFREE

#### Supply of Champix-Your Contract with Your Local Pharmacist

By stopping smoking you are doing the best thing to improve your health. Stopping smoking is much easier with help from your local stop smoking service and stop smoking medication such as Champix. As part of the service delivered by the Pharmacist they will provide the following:

- An assessment of whether you are suitable for Champix
- Friendly support and advice on how to use Champix
- Information on whether any drugs you are being prescribed by your GP will interact with Champix
- An opportunity for you to evaluate your experience-this will involve either a text message, phone call, letter in the post or email asking you to complete a questionnaire
- Sometimes Stoke-on-Trent City Council carry out audits on us, this is because they fund this service and want to ensure we are delivering high quality support. You may therefore receive a phone call asking about your experience with us.

In order to carry out the above and deliver a high quality service please can you do the following:

- Provide us with information about yourself. More detail on what information we need to collect is attached to this contract. Please keep this safely for future reference
- Do your best to attend your appointments and let us know if you can't attend
- Inform your healthcare provider of your quit attempt where requested by the Pharmacist for example if you are taking medication and you need it adjusted as part of your quit attempt
- Be honest when we ask you whether you have had a cigarette-its normal to lapse and the stop smoking service will support you to try again
- Please let us know if your details change so we can update our records
- Tell us about your experience so we can improve our service

By signing this contract you are agreeing to the above terms. This means that even when you stop using the service you may still be contacted by us and your data will still be used as described on the next page. We only keep your data for the time specified in our retention schedule or as required by law.

I (NAME) \_\_\_\_\_ agree to the above

SIGNED \_\_\_\_\_

DATE \_\_\_\_\_

Note to the Pharmacist-please ask the service user to sign 2 copies, please retain one for your records and ask the service user to keep the other.

### **HOW WE USE YOUR PERSONAL INFORMATION**

Details of your rights under data protection legislation are available at [stoke.gov.uk/dataprotection](http://stoke.gov.uk/dataprotection).

When you access a local Pharmacy for Champix as part of your stop smoking attempt the Pharmacist will collect the following information about you:

- Service User's name, address, date of birth and GP details.
- The accredited Provider who referred and the Advisor
- Date supplied and name of the Pharmacist who supplied the medication.
- Batch number and expiry date.
- Reason for inclusion.
- Advice given to Service User. Whether the Service User is entitled to free prescription charges and if so whether evidence has been seen.

We only keep this data for the time specified in our retention schedule or as required by law.

We use this data to

- Contact you to make/rearrange appointments
- Help make decisions about whether Champix is suitable for you
- Inform your GP or other appropriate health care professional, where relevant, of your quit attempt and any medication you are taking which may interfere with Champix
- Monitor, evaluate and audit the services
- For third party organisations (accredited and approved by Stoke-on-Trent City Council) to contact you for audit, evaluation, research and follow up purposes

We are able to do this because you have entered into a contract with us and we can't fulfil it without doing this

You should be aware that we have a duty to protect public funds. We may therefore use the information we have for the prevention and detection of fraud. We may share this information with other bodies for these purposes. We may also share this information with other parts of the council or other relevant organisations for purposes which may include enforcement.

If you want to speak to someone about this service please contact Rochelle Edwards 01782 231690

**Letter to Service User –GP decision to discontinue Varenicline (Champix) Treatment**

Pharmacy Name/Stamp/Tel Number

Date

Address:

Dear.....

RE: Request for *Varenicline* (Champix) to support your stop smoking attempt

Further to a recent email from your GP I would like you to stop taking the *Varenicline* (Champix) medication as it is not the best form of treatment for you. Please contact me if you would like to discuss this further.

Please take this letter to your Stop Smoking Advisor who will discuss other ways to help you to stop smoking. Please return any *Varenicline* (Champix) medication you have not used to the Pharmacy so that we can dispose of it safely.

We are sorry if this causes any problems but please continue with your attempt to stop smoking as it is the best thing you can do for the health of you and those around you.

Yours Sincerely,

Pharmacist Signature:

Print Name: