

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 EAGLES1 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
- NCSCT, Varenicline: effectiveness and safety 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.

¹ 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.

1. Reason for introducing PGD		
<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"> • The Pharmacist is accredited by Stoke-on-Trent City Council to provide stop smoking support (this includes subcontracted Pharmacists). • 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 		
2. Clinical Condition or situation to which this PGD applies		
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	<p>Criteria for inclusion</p> <p>ALL MUST APPLY</p>	<ul style="list-style-type: none"> • Service Users who have set a target quit date with an Accredited Stop Smoking Provider. • Service Users aged 18 years of age and over. • Tobacco users identified as sufficiently motivated to quit. • 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. • 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

		<p>proforma for Subsequent Supplies of Varenicline which will need to be completed.</p> <ul style="list-style-type: none"> • Service User consent has been obtained and recorded.
2.3	Criteria for exclusion	<ul style="list-style-type: none"> • Tobacco users not sufficiently motivated to quit or use Varenicline. • Service User's under 18 years of age. • 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. • Pregnancy/ Breastfeeding. • Service User's already receiving Varenicline prescribed by GP (unless an agreed transfer of care has taken place). • Service User's already using other smoking cessation pharmacotherapies. • Patient with history of renal impairment or end stage renal disease as decreased clearance by kidney increases side effects. • Service User's with history of epilepsy or history of fits or seizures. • Substance misuse patients. • Service Users who have experienced serious or significant side effects from a previous course of Varenicline. • 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 EAGLES² 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> • Service Users who have schizophrenia or schizoaffective disorder. • Service Users who are planning to use an electronic nicotine delivery device (ENDS) as part of their quit attempt. <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	<p>Effect of smoking cessation</p> <p>Physiological changes resulting from smoking cessation with or without treatment with Varenicline, may alter the</p>

² 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.

	concurrent medication]	<p>pharmacokinetics or pharmacodynamics of some medicinal products for which dose adjustment may be necessary. Examples include</p> <ul style="list-style-type: none"> • Theophylline • Warfarin • Insulin. <p>As smoking induces CYP1A2 smoking cessation may result in an increase of plasma levels of CYP1A2 substrates.</p> <p><u>Drug Interactions</u></p> <p>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><u>Neuropsychiatric symptoms</u></p> <p>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><u>History of Psychiatric Disorders</u></p> <p>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><u>Cardiovascular Events</u></p> <p>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</p>
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		<p>infarction or stroke.</p> <p><u>Hypersensitivity Reactions</u></p> <p>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><u>Cutaneous Reactions</u></p> <p>There have been post-marketing reports of rare but severe cutaneous reactions, including Stevens-Jonson Syndrome and Erythema Multiforme in Service Users 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. Note: Service Users who have had a serious allergic or skin reaction from a previous course of Varenicline are excluded.</p> <p><u>Treatment Discontinuation</u></p> <p>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><u>GP Notification</u></p> <p>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</p>
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		<p>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 UKMi "Which medicines need dose adjustment when a patient stops smoking?" UKMi Q&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.</p> <p>Treatment should not proceed if the Service User does not sign the contract.</p> <p>Under the GDPR the Pharmacist will be legally responsible for the following:</p> <ul style="list-style-type: none"> • 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 <p>The Pharmacist must:</p> <ul style="list-style-type: none"> • Ensure that staff processing the data are subject to

		<p>a duty of confidence</p> <ul style="list-style-type: none"> • 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. <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	<p>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.</p> <p>Pharmacists which are also Accredited Stop Smoking Providers should offer Service Users the option of NRT.</p> <p>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.</p> <p>Where a Service User has been referred by an Accredited Stop Smoking Service they should be referred back to the</p>

		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)
2.8	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. 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.
3. Description of treatment.		
3.1	Generic name of medicine and form (e.g. tablets)	Varenicline (Champix®) 0.5mg film coated tablets Varenicline (Champix®) 1mg film coated tablets
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	Store in a cool dry place below 30 degrees Celsius. Order supplies from licensed pharmacy wholesalers.
3.4	Dose and Frequency	In all circumstances dosing should follow the recommendations in the Varenicline Summary of Product Characteristics http://www.medicines.org.uk/emc Days 1 – 3: 0.5 mg (white tablets) once daily

		<p>Days 4 – 7:</p> <p>0.5 mg(white tablets) twice daily</p> <p>Week 2 to week 12:</p> <p>1 mg (light blue tablets) twice daily</p> <p>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>Extending course to reduce risk of relapse:</p> <p>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>Dose tapering</p> <p>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>Quit date</p> <p>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"> • 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 • Subsequent supplies using the 14-day prescription packs, complete with Patient Information leaflet, should be provided throughout the quit attempt.

		<ul style="list-style-type: none"> • The normal treatment course is 12 weeks • 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 permission from commissioner • 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. • In addition to the above, the label must also state the words “Supplied under a PGD” to help with audit purposes.
3.7	Instructions on identifying, managing & reporting adverse drug reactions	<p>For Service Users experiencing mild 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>Very Common and Common Adverse Reactions of Varenicline</p> <ul style="list-style-type: none"> • Infections and infestations <ul style="list-style-type: none"> Very common-Nasopharyngitis Common-bronchitis, sinusitis • Metabolism and nutrition disorders <ul style="list-style-type: none"> Common-weight increased, decreased appetite, increased appetite • Psychiatric Disorders <ul style="list-style-type: none"> Very Common-abnormal dreams, insomnia • Nervous System Disorders <ul style="list-style-type: none"> Very Common-headaches Common-somnolence, dizziness, dysgeusia

		<ul style="list-style-type: none"> • Respiratory, thoracic and mediastinal disorders Common-Dyspnoea, cough • Gastrointestinal disorders Very Common-Nausea Common-Gastroesophageal reflux disease, vomiting constipation, diarrhoea, abdominal distension, abdominal pain, toothache, dyspepsia, flatulence, dry mouth • Skin and subcutaneous tissue disorders Common-rash, pruritus • Musculoskeletal and connective tissue disorders Common-Arthralgia, myalgia, back pain • General Disorders and administration site conditions Common-chest pain and fatigue • Investigations Common-liver function test abnormal <p>For comprehensive information please consult the Summary of Product Characteristics which can be found at https://www.medicines.org.uk/emc/medicine/19045</p> <p>Symptoms of Stopping Smoking</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</p>
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		<p>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.</p> <p>If the Service User, family or care givers have concerns about agitation, depressed mood or changes in behaviour Varenicline should be stopped immediately.</p> <p>Please refer to current BNF and SPC for full details.</p> <p>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: www.mhra.gov.uk/yellowcard</p> <p>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 . This should only be anonymised data to comply with Information Governance requirements.</p>
3.8	Written/verbal advice for Service User before/after treatment and management	<ul style="list-style-type: none"> • Service Users should be advised to set a quit date 7 to 14 days after initiation • The major reasons for Varenicline failure are: <ul style="list-style-type: none"> - 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 Service User understands the following points: <ol style="list-style-type: none"> 1. Varenicline is not a magic cure - effort and determination are crucial 2. It works by acting on the parts of the brain which are affected by nicotine in cigarettes 3. It does not remove all temptation to smoke, but it

		<p>does make abstinence easier ('it takes the edge off the discomfort')</p> <ol style="list-style-type: none"> 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. 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. <ul style="list-style-type: none"> • For patients who have successfully stopped smoking at 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. • 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 is not required. <p><u>Alcohol</u></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</p>
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		<p>increased drunkenness, unusual or sometimes aggressive behaviour, or memory loss of events while consuming alcohol during treatment with Varenicline.</p> <p><u>Effects on ability to drive and use machines</u></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	<p>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 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	<p>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.</p>

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"> • 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 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. • PharmOutcomes should be used to ensure the Service User has not already attended an appointment with a Pharmacist for a supply of Varenicline (using unique supply reference code) • The letter should be retained, in accordance with the Data Protection Act 1998 and General Data Protection Regulations, for audit purposes. <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"> • 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

		<p>prescription charges and if so whether evidence has been seen.</p> <ul style="list-style-type: none"> • Completion of contract in line with GDPR requirements. <p>Inputting of data should be done with 48 hours following the appointment with the Service User.</p> <p>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>
4. Acknowledgements		
This Varenicline PGD has been adapted, with permission, from Worcestershire Public Health Department part of Worcestershire County Council.		
5. Audit		
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	<p>Andy Pickard, Pharmacy Advisor - NHS England North Midlands Staffordshire and Shropshire</p> <p>Dr Gill Hall, Service Development Officer - South Staffordshire LPC</p> <p>Tania Cork, Chief Officer - North Staffs and Stoke Local Pharmaceutical Committee</p> <p>Rochelle Edwards, Senior Health Improvement Specialist - Stoke-on-Trent City Council</p>
6.2	Authorisation	<p>This PGD has been approved by:</p>

Name and Designation	Organisation	Signature	Date
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.

Name	
Position	
Signature	
Date	

Appendix 1a

Initial Referral Letter for Varenicline

Stop Smoking Advisor to complete the following

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

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.

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Appendix 1b

Referral Letter for subsequent supplies of Varenicline

Stop Smoking Advisor to complete the following

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

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.

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

Appendix-5

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: