This Patient Group Direction (PGD) must only be used by registered community pharmacists who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction

for the supply of

Varenicline 0.5mg and 1mg tablets

by registered community pharmacists for

smoking cessation in combination with motivational support

Public Health Dorset

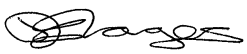
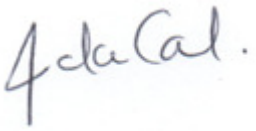
Version number: 4

Version Number:	4	Valid from:	December 2020
Review date:	May 2022	Expiry date:	December 2022

CHANGE HISTORY

Version number	Change details	Date
1	Original version adopted	March 2014
2	Routine review and update as version 1 expires 30th Sept 2016	October 2016
3	Routine review and update as version 2 expires 31st Oct 2018	October 2018
4	Routine review and update as version 3 expires 30th November 2020	November 2020

PGD DEVELOPMENT

Name	Job title and organisation	Signature	Date
Jen Lages	Health Programme Advisor, Public Health Dorset, Dorset Council		08/01/2021
Joao Da Cal	Services & Implementation Lead, Dorset Local Pharmaceutical Committee		07/01/2021
Hayley Braid	Pharmacy Technician, Dorset CCG		07/01/2021

PGD AUTHORISATION

Name	Job title and organisation	Signature	Date
Senior doctor Dr Paul Mason	Prescribing Lead, Dorset CCG		07/01/2021
Senior pharmacist Katherine Gough	Head of Medicines Management, Dorset CCG		07/01/2021
Person signing on behalf of authorising body	Dr Jane Horne Consultant in Public Health, Dorset Council		07/01/2021

PGD ADOPTION BY THE PROVIDER

Name	Job title and organisation	Signature	Date
Lead Pharmacist			

TRAINING AND COMPETENCY OF REGISTERED COMMUNITY PHARMACISTS WORKING UNDER THE PGD

	Requirements of registered community pharmacists working under the PGD
Qualifications and professional registration	• Registered Pharmacist
Initial training	• Before offering this service, all Pharmacists authorising treatment under this PGD must complete the NHS Centre for Smoking Cessation and Training (NCSCT) training and assessment online at www.ncsct.co.uk
Competency assessment	• Complete the varenicline training workbook and online questionnaire and declaration. This can be found on Provider Resources page of the Public Health Dorset Website http://www.publichealthdorset.org.uk/provider-resources/ • Able to demonstrate competency in line with the NICE Good Practice Guidance: Patient group directions: competency framework for health professionals using patient group directions
Ongoing training and competency	• The pharmacy must have a copy of the Current BNF available for reference and be familiar with the information in the BNF about the use of varenicline.
Lines of accountability	• A registered pharmacist is accountable for his or her actions in accordance with the General Pharmaceutical Council. All registered pharmacists are personally accountable for their practice and in the exercise of professional accountability there is a requirement to maintain and improve their professional knowledge and competence • The PGD may be used only within the confines of the service specification by pharmacists and pharmacies commissioned by PH Dorset
Characteristics of pharmacists making repeat supplies of varenicline: Ideally the pharmacist who is Smokestop trained and makes the initial decision to supply varenicline will be involved in supporting the patient and making repeat supplies. However if that pharmacist is absent from the pharmacy on the day that the patient requires a repeat supply, the supply may be made by the pharmacist on duty. This is based on the principle that the PGD allows for 12 weeks supply and the initiating pharmacist has authorised that quantity to be supplied in 2 week quantities.	

CLINICAL CONDITION

Clinical condition or situation to which this PGD applies	As an adjunct to smoking cessation in combination with motivational support in nicotine-dependent adults.
Inclusion criteria	• Nicotine-dependent adults identified as sufficiently motivated to quit. These people must be willing and able to attend structured stop-smoking counselling as part of the pharmacy 1:1 SmokeStop service. • 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.
Exclusion criteria	• Patients under 18 years of age • Women who are pregnant, planning pregnancy, or who are breastfeeding • Smokers not sufficiently motivated to quit and those not willing to attend check-ups • If a smokers' attempt to quit using NRT (varenicline or bupropion) is unsuccessful, do not offer varenicline within 6 months. However, if exceptional circumstances have hampered the person's initial attempt to stop smoking, it may be reasonable to try again sooner • Smokers already receiving varenicline prescribed by their GP • Patients who have experienced serious or worrying side effects from a previous course of varenicline • Patients who have previously had a hypersensitivity reaction to a medicine that involved angioedema • Patients who have previously had Stevens-Johnson Syndrome or Erythema Multiforme • Any renal impairment • Hypersensitivity to varenicline or any of its excipients • Epilepsy or history of seizures (lowering of seizure threshold has been reported) • Patients not recommended to use varenicline by their GP

Cautions (including any relevant action to be taken)	Physiological changes resulting from smoking cessation, with or without treatment with varenicline, may alter the pharmacokinetics or pharmacodynamics of some medicinal products, for which dosage adjustment may be necessary (examples include theophylline, warfarin and insulin). Clinicians should be aware of the possible emergence of serious neuropsychiatric symptoms in patients attempting to quit smoking with or without treatment. If serious neuropsychiatric symptoms occur whilst on varenicline treatment, patients should discontinue varenicline immediately and contact a healthcare professional for re-evaluation of treatment. **Neuropsychiatric Symptoms** The EAGLES study (April 2016) has provided evidence that the use of varenicline in patients with or without a history of psychiatric disorder was not associated with a significantly increased risk of serious neuropsychiatric adverse events compared with placebo. **Patients with History of Psychiatric Disorders** Smoking cessation, with or without pharmacotherapy, has been associated with the exacerbation of underlying psychiatric illness (e.g. depression). Care should be taken with patients with a history of psychiatric illness. If this is a consideration, community pharmacists should liaise with the patients' GP prior to smoking cessation. Cardiovascular disorders Patients taking varenicline should be instructed to notify their doctor of new or worsening cardiovascular symptoms and to seek immediate medical attention if they experience signs and symptoms of myocardial infarction or stroke.
Arrangements for referral for medical advice	If the patient is excluded from receiving varenicline by the PGD exclusions listed above, then they should be offered alternative smoking cessation products and advice. If the patient still wishes to obtain varenicline, with permission from the patient, the pharmacist may liaise with the patient's GP to assess whether the benefits of prescribing would outweigh the risks and/or refer the patient to the GP if still required.

Action to be taken if patient excluded	Do not supply varenicline under PGD. • Pharmacist may recommend an alternative therapy e.g. NRT • Refer to GP
Action to be taken if patient declines treatment	As above
Interactions	In patients with severe renal impairment, the concomitant use of cimetidine and varenicline should be avoided. There have been post marketing reports of increased intoxicating effects of alcohol in patients treated with varenicline.

DETAILS OF THE MEDICINE

Name, form and strength of medicine	Varenicline (Champix ®) Tablets, 0.5mg or 1mg
Legal category	Prescription Only Medicine
Indicate any off-label use (if relevant)	*Not relevant*
Route/method of administration	• Oral • Varenicline tablets should be swallowed whole with water, and can be taken with or without food • Nausea may be reduced if taken with or after food
Dose and frequency	Patients should set a quit date to stop smoking and varenicline treatment should usually start 1-2 weeks before this date. The recommended dose is 1 mg oral varenicline twice daily with a 1-week titration at the beginning and end of the 12-week period. **Days 1-3:** 0.5mg (white) once daily **Days 4-7:** 0.5mg (white) twice daily **Day 8 to end of treatment:** 1mg (blue) twice daily **End of treatment reduction can commence at week 10 for completion by week 12 (titration pack in reverse with clear instructions), patient to take:**

	1mg (blue) twice daily for 7 days THEN 0.5mg (white) twice daily for 4 days THEN 0.5mg daily for 3 days • Tablets should be swallowed whole with plenty of water and can be taken with or without food • Patients who cannot tolerate side effects but are still motivated to continue treatment may have their dose lowered temporarily or permanently to 0.5mg twice daily. For patients taking this dose, titration for the last week by taking 0.5mg daily is recommended
Quantity to be administered and/or supplied	• Provision for the first two weeks supply is provided as a titration pack, which contains one clear blister of 11 x 0.5 mg film-coated tablets and a second clear blister of 14 x 1 mg film-coated tablets • Weeks 1 and 2 (initial supply): following a satisfactory pharmacist clinical assessment the patient should be supplied with a 14-day initiation pack and should set a quit date 7–14 days after initiation. • Weeks 3 and 4: following a satisfactory pharmacist clinical check, the pharmacist should: o confirm that the patient has quit (or set a quit date if the patient is still within the initial 14-day treatment period) o confirm that the GP has not raised any objection to the patient being supplied with varenicline, then make a varenicline supply 28 x 1mg, or if a decision has been taken to reduce the dose following a review of side effects supply 56 x 0.5mg • Further supplies of the 1mg tablet should be made at either two-weekly or four-weekly intervals following a satisfactory pharmacist clinical assessment. If the patient has had the dose reduced to 0.5mg a four-week supply (56 x 0.5mg) at four weekly intervals should be made • A 14-day treatment initiation pack can be used in reverse for the final two weeks of treatment if appropriate (see 'Dose and frequency' section above)
Maximum or minimum treatment	The normal treatment course is up to 12 weeks for 1mg twice daily and up to 14 weeks for 0.5mg twice daily (due to larger minimum

<table>
<tr><td>period</td><td>original pack size).</td></tr>
<tr><td>Adverse effects</td><td>
Very common (≥ 1/10)
<table>
<tr><td>Nasopharyngitis</td><td>Nausea</td></tr>
<tr><td>Insomnia</td><td>Headache</td></tr>
<tr><td>Abnormal dreams</td><td></td></tr>
<tr><td></td><td></td></tr>
</table>
Common (≥ 1/100 to < 1/10)
<table>
<tr><td>Bronchitis</td><td>Rash*</td></tr>
<tr><td>Weight increase</td><td>Sinusitis</td></tr>
<tr><td>Decreased appetite</td><td>Increased appetite</td></tr>
<tr><td>Diarrhoea</td><td>Vomiting</td></tr>
<tr><td>Abdominal pain</td><td>Gastro oesophageal reflux disease</td></tr>
<tr><td>Dyspepsia</td><td>Constipation</td></tr>
<tr><td>Flatulence</td><td>Abdominal distension</td></tr>
<tr><td>Somnolence</td><td>Toothache</td></tr>
<tr><td>Dysgeusia</td><td>Dry mouth</td></tr>
<tr><td>Dyspnoea</td><td>Dizziness</td></tr>
<tr><td>Back pain</td><td>Cough</td></tr>
<tr><td>Live function test abnormal</td><td>Myalgia/Arthralgia</td></tr>
<tr><td>Pruritus*</td><td>Fatigue</td></tr>
<tr><td>Chest pain</td><td></td></tr>
</table>
*Severe cutaneous reactions, including Stevens-Johnson Syndrome, Erythema Multiforme and angioedema have been reported, therefore patients should discontinue treatment with varenicline at the first sign of rash or skin reaction and report this side effect to their GP or pharmacist immediately.

Patients should also be asked at every appointment about nicotine withdrawal symptoms, including mood changes. Smoking cessation with or without treatment is associated with various symptoms. For example, dysphoria or depressed mood; insomnia, irritability, frustration or anger; anxiety; difficulty concentrating; restlessness;
</td></tr>
</table>

	decreased heart rate; increased appetite or weight gain have been reported in patients attempting to stop smoking. Clinicians should be aware of the possible emergence of serious neuropsychiatric symptoms in patients attempting to quit smoking **with or without** treatment. If serious neuropsychiatric symptoms occur patients should be advised to discontinue treatment and seek prompt medical advice. If the patient develops suicidal thoughts or behaviour they should be told to stop treatment and contact their GP immediately. **For a full list of adverse effects, please refer to the BNF or the summary of product characteristics.** **Report all serious suspected adverse reactions to the MHRA via the Yellow Card system (even if they are listed in the BNF or above). Serious reactions are those with are fatal, life threatening, disabling, incapacitating or which result in prolonged hospitalisation and/or are medically significant.**
Records to be kept	Records of the consultation must be uploaded onto PharmOutcomes using the template specified by Public Health Dorset. This information automatically prompts payment as well as acting as a record which can be referred to later. Anonymised data from PharmOutcomes is shared with the commissioner for monitoring and audit purposes only. In addition: • The pharmacy must make a record of the supply on the patient medication record (PMR) • The person's GP must be informed via NHSmail
Follow-up advice to be given to patient or carer	Patients can benefit from additional lifestyle advice and support from LiveWell Dorset www.livewelldorset.co.uk 0800 8401628 / 01305 233105

PATIENT INFORMATION

Information to be given to patient or carer	• Patients must be informed that information relating to the supply of varenicline under PGD will be passed on to their GP and the SmokeStop Service to ensure proper record keeping and patient safety
	• Advice to patients should include specific advice on dosage, duration of treatment, and side effects
	• All suspected side effects should be reported to the MHRA via the Yellow Card system
	• Patients should be advised to **discontinue treatment** and seek prompt medical advice if they, or their family or carers notice that the patient has developed increased anxiety, depression, aggression, irrational behaviour, psychosis or suicidal ideation
	• Severe cutaneous reactions, including Stevens-Johnson Syndrome, Erythema Multiforme and angioedema have been reported, therefore patients should **discontinue treatment** with varenicline at the first sign of rash or skin reaction and report this side effect to their GP or pharmacist immediately
	• Patients should be advised on obtaining further supplies of varenicline and the need to attend at 2-weekly intervals
	• 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 patients. The pharmacist should inform the patient accordingly and discuss or consider the need for dose tapering
	• General smoking cessation advice should also be given, particularly with regard to:
	  ○ Withdrawal symptoms
	  ○ Possible changes in the body on stopping smoking, e.g. weight gain
	
	Effect of Smoking Cessation
	• Cigarette smoke stimulates a liver enzyme responsible for metabolising some medicines in the body, such as theophylline, warfarin, clozapine and insulin, meaning that the metabolism of these medications increases. Patients should be warned that 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.
	• If a patient is a diabetic or is taking theophylline/aminophylline, warfarin or antipsychotic medication e.g. Clozapine ensure

	their GP and treating physician is notified of their quit attempt/use of varenicline using the letter provided with this PGD. ○ When the patient stops smoking, metabolism of theophylline is reduced which could cause plasma theophylline levels to rise, possibly to toxic levels if the dose of theophylline is not adjusted. Signs of theophylline toxicity are: - vomiting, dilated pupils, sinus tachycardia and hyperglycaemia ○ Patients on warfarin, should advise the clinic of their intention to quit smoking using varenicline when they next attend for a blood test ○ Patients taking antipsychotics (and other medications effected by smoking cessation) should advise their treating physician of their intention to stop smoking prior to quitting ○ Patients on insulin may be supplied with varenicline. However, they should be advised to monitor their blood glucose levels closely **Please note:** The above list of medications is not exhaustive and further clarification using relevant reference sources, cross referencing the patient's current medication profile, should be made by the pharmacist supplying any smoking cessation product. Patients wanting more information can be referred to: www.livewelldorset.co.uk 0800 8401628 / 01305 233105

APPENDICES

Appendix A Key references

1. Summary of Product Characteristics for varenicline (Champix®), accessed via: http://www.medicines.org.uk/emc/medicine/19045/SPC/CHAMPIX++0.5+mg+film-coated+tablets%3b+CHAMPIX++1+mg+film-coated+tablets/.
2. The current edition of the BNF (www.bnf.org)
3. NHS Executive HSC 2000/026. Client Group Directions (England Only), London 2000.

Sources of further information

NICE Smoking Cessation – bupropion and nicotine replacement therapy: http://guidance.nice.org.uk/TA39

NICE Smoking cessation – varenicline: http://guidance.nice.org.uk/TA123

NCSCT / Public Health England – local stop smoking services: service and delivery guidance 2014

https://www.ncsct.co.uk/usr/pub/LSSS_service_delivery_guidance.pdf

Public Health England - Health matters: stopping smoking – what works?

https://www.gov.uk/government/publications/health-matters-stopping-smoking-what-works/health-matters-stopping-smoking-what-works

NICE stop smoking interventions and services

https://www.nice.org.uk/guidance/ng92

Action on Smoking and Health "ASH" (UK) website

https://ash.org.uk/home/

National Pharmacy Association "NPA" smoking cessation resources

https://www.npa.co.uk/services-and-support/business-support/promoting-your-pharmacy/business-profiles/smoking-cessation/

Appendix B Health professionals' agreement to practise

Patient Group Direction for the Supply and/or Administration of varenicline (Champix®)

This Patient Group Direction is for use in

……Pharmacy ☐

Or by a locum pharmacist in pharmacies approved to offer the service ☐

The direction must be read, agreed to and signed by each of the pharmacists who work within it. All professions must act within their appropriate Code of Professional Conduct. One copy should be given to each pharmacist with the master copy being kept by the manager of each pharmacy approved to offer the service.

I confirm that I have read and understood the content of this Patient Group Direction and that I have completed the appropriate training in order to implement it effectively. I agree to work within its parameters.

Name of community pharmacist	**Signature**	**Senior representative authorising community pharmacist**	**Date**