

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: 3


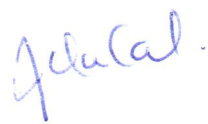
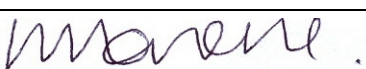
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CHANGE HISTORY

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

PGD DEVELOPMENT

Name	Job title and organisation	Signature	Date
Chris Ricketts	Head of Programmes, Public Health Dorset, Dorset County Council		22/11/18
Joao Da Cal	Services & Implementation Lead, Dorset Local Pharmaceutical Committee		29/11/18
Hayley Braid	Pharmacy Technician, Dorset CCG		13/12/18

PGD AUTHORISATION

Name	Job title and organisation	Signature	Date
Senior doctor Dr Paul Mason	Prescribing Lead, Dorset CCG		19/12/18
Senior pharmacist Katherine Gough	Head of Medicines Management, Dorset CCG		20/12/18
Person signing on behalf of authorising body	Dr Jane Horne Consultant in Public Health, Dorset County Council		29/11/18

PGD ADOPTION BY THE PROVIDER

Name	Job title and organisation	Signature	Date
Lead Pharmacist			

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TRAINING AND COMPETENCY OF REGISTERED COMMUNITY PHARMACISTS WORKING UNDER THE PGD

	Requirements of registered community pharmacists working under the PGD
Qualifications and professional registration	<ul style="list-style-type: none"> Registered Pharmacist
Initial training	<ul style="list-style-type: none"> Before offering this service, all Pharmacists authorising treatment under this PGD must complete the NHS Centre for Smoking Cessation and Training (NCST) training and assessment online at www.ncst.co.uk
Competency assessment	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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
<p>Characteristics of pharmacists <u>making repeat supplies of varenicline:</u></p> <p>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.</p>	

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CLINICAL CONDITION

Clinical condition or situation to which this PGD applies	<p>As an adjunct to smoking cessation in combination with motivational support in nicotine-dependent adults.</p>
Inclusion criteria	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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

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<p>Cautions (including any relevant action to be taken)</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 dosage adjustment may be necessary (examples include theophylline, warfarin and insulin).</p> <p>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.</p> <p>Neuropsychiatric Symptoms</p> <p>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.</p> <p>Patients with History of Psychiatric Disorders</p> <p>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.</p> <p>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.</p>
<p>Arrangements for referral for medical advice</p>	<p>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.</p> <p>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.</p>

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Action to be taken if patient excluded	Do not supply varenicline under PGD. <ul style="list-style-type: none"> • Refer to GP • Pharmacist may recommend an alternative therapy e.g. NRT
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 <u>off-label use</u> (if relevant)	<i>Not relevant</i>
Route/method of administration	<ul style="list-style-type: none"> • 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	<p>Patients should set a quit date to stop smoking and varenicline treatment should usually start 1-2 weeks before this date.</p> <p>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.</p> <p>Days 1-3: 0.5mg (white) once daily Days 4-7: 0.5mg (white) twice daily Day 8 onwards: 1mg (blue) twice daily</p> <p>End of treatment reduction (titration pack in reverse) 1mg (blue) twice daily for 7 days then 0.5mg (white) twice daily for 4 days then 0.5mg daily for 3 days</p>

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	<ul style="list-style-type: none"> • 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 • From this point, maintenance packs are supplied for 2 weeks at a time • For the final two weeks a titration pack should be provided to be used in reverse • 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	12 weeks supply of varenicline. (Two weeks supply at a time in line with the requirements of the pharmacy SmokeStop service specification)
Maximum or minimum treatment period	Maximum 12 weeks supply of varenicline.

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Adverse effects	Very common ($\geq 1/10$)	
	Nasopharyngitis	Myalgia
	Insomnia	Chest pain
	Abnormal dreams	Nausea
	Headache	
	Common ($\geq 1/100$ to $< 1/10$)	
	Bronchitis	Rash*
	Weight increase	Sinusitis
	Decreased appetite	Increased appetite
	Diarrhoea	Vomiting
	Abdominal pain	Gastro oesophageal reflux disease
	Dyspepsia	Constipation
	Flatulence	Abdominal distension
	Somnolence	Toothache
	Dysgeusia	Dry mouth
	Dyspnoea	Dizziness
	Back pain	Cough
	Live function test abnormal	Arthralgia
	Pruritus*	Fatigue
	<p>*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.</p> <p>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; decreased heart rate; increased appetite or weight gain have been</p>	

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	<p>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.</p> <p>If the patient develops suicidal thoughts or behaviour they should be told to stop treatment and contact their GP immediately.</p> <p>For a full list of adverse effects, please refer to the BNF or the summary of product characteristics.</p> <p>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 which are fatal, life threatening, disabling, incapacitating or which result in prolonged hospitalisation and/or are medically significant.</p>
<p>Records to be kept</p>	<p>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.</p> <p>In addition:</p> <ul style="list-style-type: none"> • The pharmacy must make a record of the supply on the patient medication record (PMR) • The person's GP must be informed via fax
<p>Follow-up advice to be given to patient or carer</p>	<p>Patients can benefit from additional lifestyle advice and support from LiveWell Dorset www.livewelldorset.co.uk 0800 8401628 / 01305 233105</p>

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PATIENT INFORMATION

Information to be given to patient or carer	<ul style="list-style-type: none">• 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:<ul style="list-style-type: none">○ Withdrawal symptoms○ Possible changes in the body on stopping smoking, e.g. weight gain <p>Effect of Smoking Cessation</p> <ul style="list-style-type: none">• 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
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	<p>their GP and treating physician is notified of their quit attempt/use of varenicline using the letter provided with this PGD.</p> <ul style="list-style-type: none"> ○ 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 <p>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.</p> <p>Patients wanting more information can be referred to: www.livewelldorset.co.uk 0800 8401628 / 01305 233105</p>
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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/RPSGB/Pharmacy Health Link: Helping smokers to stop: advice for pharmacists in England, August 2005, <http://www.publichealth.nice.org.uk/page.aspx?o=517943>

NHS smoking cessation services: service and monitoring guidance (www.dh.gov.uk/assetRoot/04/07/81/16/04078116.pdf)

NICE Smoking Cessation Guidance: <http://guidance.nice.org.uk/PHI1>

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

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

ASH (UK) website: http://www.newash.org.uk/ash_home.htm

NPA – Stop smoking – Implementing a community pharmacy scheme in England: http://www.npa.co.uk/news_uploads/575979_web_only.pdf

Towards a smoke free England: Brief interventions for stopping smoking by pharmacists and their staff: http://www.pharmacymeetpublichealth.org/pdf/SMOKING_report.pdf

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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

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