

**PATIENT GROUP DIRECTION (PGD)
For the supply of VARENICLINE (CHAMPIX®) BY
AUTHORISED PGD ACCREDITED COMMUNITY
PHARMACISTS WORKING IN NOTTINGHAMSHIRE**

Issued on:	1 st August 2016
Expiry date:	31 st March 2019
Review date:	1 st April 2018

PATIENT GROUP DIRECTIONS – under Human Medicines Regulations 2012 A
PGD is a specific written instruction for the supply or administration of named medicines in an identified clinical situation. It applies to groups of clients or other service users who may not be individually identified before presentation for treatment. It is drawn up locally by doctors, pharmacists and other appropriate professionals, and authorised by the relevant appropriate body.

Change History

Version	Changes from previous approved PGD	Date of Review
1.0	Nil : this is the first version	
4.0	Removal of requirement to record batch and expiry date	09.03.2016
5.0	Review / update due to removal of black triangle status	July 2016

1. Characteristics of persons authorised to operate this PGD	
Qualification required	Accredited pharmacists in an approved community pharmacy. Pharmacists must be registered with the General Pharmaceutical Council (GPhC).
Training Requirements	- Pharmacists wishing to supply prescription only medicines (POMs) via a Patient Group Direction (PGD) must complete face-to-face PGD training provided by Solutions 4 Health (S4H) and stay up to date accessing on line modules e.g. NCSCT (accessed via CPPE). CPPE declaration of competence - Understands the legislation surrounding and is competent to work under PGDs. - Understands their professional duties in terms of confidentiality. - Has read and understood this PGD and ideally has assessed themselves as competent using the NICE Competency Framework for health professionals using Patient Group Directions NICE PGD resources - Has completed the S4H pre-reading to include: NCSCT service and delivery guidance; varenicline SPC ; BMJ systematic review ; NICE PGD guidance ; NCSCT varenicline: effectiveness and safety (see also further reading). <i>Accepts personal responsibility for working within the PGD, understands the legal implications of doing so and works within the scope of the PGD.</i> <i>It is the responsibility of the individual to keep up to date with any changes to manufacturer's literature or other changes to guidance that may affect this PGD or the operation of PGDs generally.</i> - Pharmacists are working as part of the wider healthcare team providing support for smoking cessation and should not feel isolated. Pharmacists can contact S4H colleagues for advice.
2. Clinical Condition to which the PGD applies	
Define situation/condition	Supply of varenicline by accredited community pharmacists to clients accessing smoking cessation services through S4H in accordance with S4H Service Level Agreement (SLA), as commissioned by Nottinghamshire County Council.
Criteria for Inclusion	Client meets all the following criteria:

	• Dependent tobacco users identified as sufficiently motivated to quit with varenicline or are allergic to nicotine or any excipients of nicotine replacement therapy products. • Clients aged 18 and over • The client agrees to receive weekly behavioural support according to the agreed protocol. • A full medical history is taken and documented and there are no contraindications or cautions for treatment with varenicline (see Criteria for exclusion and referral). • Client consent has been obtained and recorded. • Client has consented for information to be shared with GP and recorded on S4H client assessment form and emailed or securely faxed to GP within 72 hours of supply, as per the instructions on the supplementary forms.
Criteria for Exclusion	Client is excluded for one or more of the following reasons: • Tobacco users not sufficiently motivated to quit or use varenicline. • Client has had an unsuccessful attempt to quit using varenicline on the programme in the last 12 months • Client under 18 years of age • Hypersensitivity to varenicline or any of the product excipients. (check manufacturer's SPC for details) • Clients with a history of, or current, moderate or severe renal impairment • Pregnant or breastfeeding women • Valid consent not provided. • Client not registered with a GP • No consent to share information with GP. • Other licensed smoking cessation therapies currently being used by the client. • Clients with a history of seizures or with other conditions that lower the seizure threshold. • Clients with a history of cardiovascular disease • Client is taking methadone
Clients who may receive the supply of varenicline Precautions and good history taking:	• History of psychiatric illness / psychiatric symptoms Care should be taken with patients with a previous history of psychiatric illness / psychiatric symptoms (schizophrenia, bipolar disorder and major depressive disorder) - including any psychiatric condition requiring medication or psychotherapy in past 5 years and clients should be monitored closely and advised accordingly.

	• Important SPC changes June 2016: As a result of the largest comparative randomised controlled trial of approved smoking cessation medications, the black triangle and associated warning have been removed. SPC updated June 2016 states “The use of varenicline in patients with or without a history of psychiatric disorder was not associated with an increased risk of serious neuropsychiatric adverse events in the composite endpoint compared with placebo” Pharmacists working under this PGD & trained stop smoking advisors, should be aware of the possible emergence in rare circumstances of significant depressive symptoms in clients undergoing a smoking cessation attempt, and should advise patients accordingly. Depressed mood, rarely including suicidal ideation and suicide attempt, may be a symptom of nicotine withdrawal. In addition, smoking cessation, with or without pharmacotherapy, has been associated with exacerbation of underlying psychiatric illness (e.g. depression). Advice from the Medicines and Healthcare Products Regulatory Agency (MHRA) and Commission on Human Medicines (CHM) & SPC: Varenicline should be stopped immediately if agitation, depressed mood, or changes in behaviour are observed that are of concern to the client, family, or caregivers. In many post-marketing cases, resolution of symptoms after discontinuation of varenicline was reported, although in some cases the symptoms persisted; therefore, ongoing follow up should be provided until symptoms resolve. See also “<i>Advice to clients</i>” below:
Action if client declines or is not suitable based on exclusion criteria	Discuss alternative treatment options if suitable and/or offer a referral to their GP to provide varenicline under their supervision if clinically appropriate. Ongoing behavioural support can continue with the S4H advisor.

3. Description of the treatment	
Name of treatment	Varenicline (Champix®) 0.5mg film coated tablets Varenicline (Champix®) 1mg film coated tablets
Legal status of Medicine	Prescription Only Medicine (POM)
Route of administration	This is an oral formulation (tablet).
Dose and frequency of administration	Smokers should set a date to stop smoking and treatment with varenicline should commence 1 to 2 weeks before this date. Day 1-3 : 0.5mg (white tablets) once a day Day 4-7 : 0.5mg twice a day Day 8 – end of treatment : 1mg (blue tablets) twice a day (can be reduced to 0.5mg twice a day if not tolerated due to adverse effects) Varenicline dose tapering can be commenced at week 10 to be completed by week 12 (if client agrees). Consider supply of a starter pack at reverse dosage, with clear instructions, where client takes: • one week of varenicline 1mg twice daily • THEN 0.5mg twice daily for four days • THEN one 0.5mg tablet once daily for three days The total period of treatment is 12 weeks and cannot be exceeded beyond 12 weeks. If client requires further stop smoking intervention after 12 weeks, they should be referred to their GP. Tablets should be swallowed whole with plenty of water and can be taken with or without food (this will help minimise possible nausea)
Duration of treatment	The period of treatment is 12 weeks.
Contra-indications	Known hypersensitivity to the active substance or any of the excipients, see SPC . See also exclusion criteria.
Cautions	Caution should be exercised in clients taking cinacalcet, ropinirole, theophylline, warfarin or insulin due to potential changes in pharmacokinetics following smoking cessation – GP must be informed that dose adjustment / closer monitoring of these drugs may be required once quit achieved. Clients on insulin should be advised to monitor their blood glucose closely.

Drug Interactions	Trial data shows no clinically meaningful drug interactions. No dosage adjustment of varenicline or co-administered medicinal products is recommended. Consult manufacturer's SPC for further information. It should be noted that the metabolism of some drugs will be affected if a client stops smoking, as cigarette smoke interacts with some medicines by stimulating the cytochrome P450 enzymes (particularly CYP1A2). The medicines in which this is of clinical importance are: warfarin, theophylline, cinacalcet, ropinirole, methadone, insulin, and some antipsychotics including chlorpromazine, clozapine, and olanzapine.(see <i>Inclusion and Exclusion criteria</i> for this PGD and UKMI Q&A 136.4 in References)
Side effects	Very common and common side effects include: • GI disturbances (including nausea which affects about 30% of clients - this can be reduced by taking the tablet after food and with a full glass of water) • Nasopharyngitis, bronchitis, sinusitis • Dyspnoea, cough • Sleep disorders, abnormal dreams, insomnia • Headache • Appetite changes, increased weight, decreased weight • Dry mouth, taste disturbances • Drowsiness • Dizziness, rash, pruritus • Chest pain, fatigue • Arthralgia, myalgia, back pain Abnormal liver function tests are also reported as a common event. For the full list of side effects refer to the varenicline SPC
Quantity to supply	1st Consultation (initial) – 2 weeks (starter pack of 0.5mg x 11 tablets and 1mg x 14 tablets) 2nd Consultation – 2 weeks (1mg or 0.5mg x 28 tablets) 3rd Consultation – 2 weeks (1mg or 0.5mg x 28 tablets) 4th Consultation – 2 weeks (1mg or 0.5mg x 28 tablets) 5th Consultation – 2 weeks (1mg or 0.5mg x 28 tablets) 6th Consultation – 2 weeks (1mg or 0.5mg x 28 tablets)

Storage	Blister: Store below 30°C HDPE Container: This medicinal product does not require any special storage conditions
Labelling	The product must be labelled as for a dispensed medicine and bear all relevant cautionary wording as stated in the BNF. Titration packs must bear the instruction to “take as directed on enclosed leaflet” and other packs to “Take one tablet twice a day”
Reporting Adverse Drug Reactions (ADRs)	All actual or suspected adverse reactions must be reported to the Commission on Human Medicines via the Yellow Card Scheme. (see the back of the BNF for details or report online at Yellow Card). An adverse reaction must be reported even if it is not certain that the drug has caused it, or if the reaction is well recognised, or if other drugs have been given at the same time. ADR's must also be reported to S4H and the client's GP and recorded in the client's record.
Advice to clients	The client should be informed of the risks and benefits of using varenicline to support a smoking cessation attempt in order that the client can make an informed decision. Advice to clients should include specific advice on dosage, method of administration and side effects of varenicline. Clients should be made aware of the following possible adverse reactions: <u>MHRA / CHM advice: Suicidal behaviour and varenicline</u> Clients should be advised to discontinue treatment and seek prompt medical advice if they develop agitation, depressed mood of concern or suicidal thoughts. It is important that client be encouraged to declare any current or history of mental illness (see information on precautions). Pharmacists should be aware of the possible stigma associated with the declaration of such conditions and therefore ensure that the client has sufficient privacy during the initial consultation to facilitate such conversations. <u>Cardiovascular symptoms</u> Clients should inform their GP of any new or worsening cardiovascular symptoms, and seek urgent medical attention if they experience signs or symptoms of myocardial infarction or stroke.

	<u>Hypersensitivity reactions</u> If the client experiences swelling of the face, mouth, neck or extremities, whilst taking varenicline, they should discontinue treatment and seek medical advice immediately. <u>Cutaneous reactions (rare)</u> If the client develops a rash or skin reaction whilst taking varenicline, they should discontinue treatment and seek medical advice immediately. Varenicline may enhance the effects of alcohol. It is important to make sure that the client understands the following points: 1. Varenicline is not a panacea: 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 the temptation to smoke, but it does make abstinence easier (it takes the edge off the discomfort by reducing the severity of tobacco withdrawal symptoms such as craving to smoke, irritability, poor concentration and low mood) 4. Varenicline is considered safe, but about a third of clients may experience mild nausea usually about 30 minutes after taking it. This reaction often diminishes gradually over the first few weeks, and most clients tolerate it without problems. 5. If the client is finding the side effects intolerable, they should seek advice from their S4H advisor or pharmacist. The following general advice should also be given: • The importance of follow-up and how to obtain further supplies • Possible changes in the body on stopping smoking e.g. weight gain • Varenicline may cause drowsiness. If affected, the client should be advised not to drive or operate machinery • Clients on insulin should monitor their blood glucose closely • If the client forgets to take varenicline, they should not take a double dose to make up for the one they missed. It is
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	important they take the medication regularly and at the same time each day. If they have forgotten to take a dose, they should take it as soon as they remembered but if it is almost time for the next dose they should not take the tablet they have missed At the end of treatment, discontinuation of varenicline has been associated with an increase in irritability, urge to smoke, and/or insomnia in up to 3% of clients. The major reasons for varenicline failure are: • Unrealistic expectations; • Lack of preparation for the fact that tablets may cause nausea; • Insufficient support from trained smoking cessation advisor
Informed Consent	Client must be informed that information relating to the supply of varenicline under a PGD needs to be passed to other health service organisations, in particular their GP and S4H to ensure proper record keeping and client safety.
Record keeping	Record keeping entries should be made on PharmOutcomes and should include: • Client's name, address, date of birth and GP details • Date supplied & name of the pharmacist who supplied the medication • Reason for inclusion • Advice given to client • Details of any adverse drug reaction and actions taken including documentation in the client's medical record via GP • A record of the supply must be made on the pharmacy client medication record system • If computer access is not available record information on blank template and record on pharmoutcomes as soon as possible Following the last consultation, the Record of Supply (Form 1) and the original Assessment Proforma (Form 3) must be retained by the pharmacy for at least two years. Pharmacies must participate in annual clinical audit if requested by the service provider.

Documents to be used in conjunction with the PGD	See Appendix 1
Further reading for pharmacists	(EAGLES) Neuropsychiatric Safety and Efficacy of Varenicline, Bupropion and Nicotine Patch in Smokers with and without psychiatric disorders. Double-blind, randomised, placebo-controlled trial. Published April 2016, The Lancet. Gibbons, R.D & Mann, J.J.: Varenicline, Smoking Cessation, and Neuropsychiatric Adverse Events; Am J Psychiatry. Dec 20 2012: AiA 1-8. Thomas, K.H. et al: Smoking cessation treatment and risk of depression, suicide, and self-harm in the Clinical Practice Research Datalink: prospective cohort study; BMJ 2013;347:f5704. Foulds, J. et al. Effect of Varenicline on Individual Nicotine Withdrawal Symptoms: A Combined Analysis of Eight Randomized, Placebo-Controlled Trials; Nicotine & Tobacco Research, Volume 15, Number 11 (November 2013) 1849– 1857.

4. Authorisation of PGD			
NOTTINGHAMSHIRE COUNTY COUNCIL AUTHORISATION OF PATIENT GROUP DIRECTION FOR THE SUPPLY OF Varenicline for smoking cessation By community pharmacies			
Clinical authorisation			
Name	Job Title and Organisation	Signature	Date
Dr Asiya Kaiser	Clinical Lead, Solutions 4 Health LTD		25.07.2016
Darush Attar-Zadeh	Lead Pharmacist and Trainer Solutions 4 Health LTD		25.07.2016
Nick Hunter	Nottinghamshire Pharmacist / Prescribing Representative		22.03.2016
Commissioner authorisation			
Barbara Brady	Interim Director of Public Health		
Version Control			
PGD comes into force	1 August 2016		
PGD expires	31 st March 2019		
Version	5.0		

5. PGD Development Team

Darush Attar-Zadeh	Pharmacist & National Trainer Smoking Cessation
Dr Asiya Kaiser	Clinical Lead, Solutions 4 Health
Leena Sankla	Director of Public Health and Lifestyle Services, Solutions 4 Health
Nick Hunter	Chair, Nottinghamshire LPC

6. References

British National Formulary (BNF) accessed December at

<http://www.evidence.nhs.uk/formulary/bnf/current/4-central-nervous-system/410- drugs-used-in-substance-dependence/4102-nicotine- dependence/varenicline/varenicline>

CHAMPIX® (varenicline) Summary of Product Characteristics (SmPC) and Package Leaflet now updated to Include New Safety & Efficacy Data from the EAGLES Clinical Trial Following Positive Opinion by CHMP1 July 2016

http://www.ncsct.co.uk/usr/pub/Varenicline_SPC_update.pdf

Summary of Product Characteristics & Client Information Leaflet for Champix® (updated 6th July 2016) accessed July 2016

<http://www.medicines.org.uk/emc/medicine/19045#PRODUCTINFO>

Medicines and Health Product Regulatory Agency (MHRA) Safety Alerts: Nov 2008 and subsequent updates.

www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/index.htm

UK Medicines Information (UKMI) bulletin Q&A 136.4 Which medicines need dose adjustment when a client stops smoking? August 2012

Varenicline for smoking cessation. NICE technology appraisal TA 123, July 2007; accessed December 2015 at www.nice.org.uk

Smoking cessation services. NICE Public Health Guidance 10; last updated Nov 13; accessed December 2015 at www.nice.org.uk



7. AUTHORISATION OF NAMED PHARMACISTS TO OPERATE UNDER THIS PGD

Agreement by Pharmacist

Authorisation

This Patient Group Direction gives authority for:

(PRINT NAME of APPROVED PHARMACIST)

To supply Varenicline (Champix) 0.5mg and 1mg to clients

(NAME OF PHARMACY)

(ADDRESS)

Requirements for a participating pharmacist

- To have satisfactorily completed the required training;
- To have been accredited as an approved practitioner within this scheme;
- To have been advised to have appropriate indemnity insurance;
- To maintain clinical knowledge appropriate to their practice by attending relevant study days or completing courses and to make themselves aware of appropriate current literature such as the latest SPC;
- To act as an approved practitioner within the terms of the Patient Group Directions and Proformas and to supply accordingly;
- To work in an approved pharmacy

S4H (Smokefreelife Nottinghamshire) will accept responsibility for only the accuracy and clinical content of the Patient Group Direction and Assessment Proforma.

Pharmacist declaration

I have received, read and fully understand the following documents:

- The general policy on pharmacist supply under Patient Group Directions issue by S4H;
- The relevant Patient Group Direction;
- The forms associated with Patient Group Direction

I have received the training which approved practitioners must undertake before being authorised to supply varenicline under the relevant Patient Group Direction.

I agree to act as an approved practitioner within the terms of the Patient Group Direction and Assessment Proforma and to supply accordingly.

I understand that by agreeing to act as an approved practitioner under the Patient Group Direction and Service Level Agreement I am adjusting my scope of professional practice.

Pharmacist Signature: _____ **Date:** _____

Appendix 1: Supporting documents for this PGD

Smokefreelife Nottinghamshire 02 Flow chart for supply only and supply/advice

Smokefreelife Nottinghamshire 03 Policy of supplying Varenicline under a PGD for smoking cessation

Smokefreelife Nottinghamshire Form 1 – The PGD Varenicline supply only form (Pharmacy use only)

Smokefreelife Nottinghamshire Form 2 – The GP & S4H notification of supply form (Pharmacy use only)

Assessment proforma Form 3– complete via PharmOutcomes

Smokefreelife Nottinghamshire Form 4 – Client assessment form (Advisor use only – for information)

Smokefreelife Nottinghamshire Form 5 – Pharmacist letter of recommendation (Advisor use only)

Smokefreelife Nottinghamshire Form 5a – Letter of recommendation for follow up supplies only (Advisor use only – for information)

Monthly claims – complete via PharmOutcomes

See notes within the PGD regarding retention of information.