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PATIENT GROUP DIRECTION (PGD)

For the Supply of Varenicline

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SOMERSET

PATIENT GROUP DIRECTION (PGD) FOR: **THE SUPPLY OF VARENICLINE**

VERSION CONTROL

Document Status:	Draft
Version:	1.7

Document Change History		
Version	**Date**	**Comments**
1.1	11 June 2015	Signature sheet amended, return a copy to Solutions4Health
1.2	July 2015	Updating signature sheets
1.3	March 2017	Changed all references to Solutions4Health to Somerset County Council
1.4	July 2018	Updated in line with revised SPC and removal of black triangle status
1.5	February 2019	Remove references to supply of Bupropion (Zyban) and update the PGD in line with the SFLS Treatment Protocol V010219
1.6	October 2020	Remove references to Champix as a brand name and replace with Varenicline Update information on associated risk of severe renal impairment Correction to dosage for intolerable adverse reactions with full dose Inclusion of dose tapering at end of course to reduce risk of relapse Removal of total dose number to supply / administer (not required) Update ongoing reference of BNF online only
1.7	November 2022	Change references to varenicline as the product has been off patent since September 2021. Change reference to Stop Smoking Adviser to Stop Smoking Practitioner (SSP)

Author	Caroline Brooks
Document reference	

PATIENT GROUP DIRECTION (PGD) FOR THE SUPPLY OF VARENICLINE

Drug: Varenicline 500microgram tablets and 1mg tablets
Condition: Patients accessing Stop Smoking Services in need of pharmacological treatment
Professional Group: Pharmacists

You must be Authorised by Name, Under the Current Version of this PGD before you attempt to work according to it

Clinical Condition		
1.	**Define condition / indication**	Patients accessing Stop Smoking Services in need of pharmacological treatment.
2.	**Inclusion criteria**	• Clients receiving group or individual advice and support from smoking cessation services either provided directly by Smokefreelife Somerset, or by Community Pharmacies approved to provide smoking cessation services by Somerset County Council • Tobacco users aged 18 years and above who are sufficiently motivated to quit • Clients willing to work with a Stop Smoking Practitioner (SSP) towards setting a quit date and returning for support • Clients who have had unsuccessful quit attempts in the past may be considered for treatment under this PGD • A full medical history is taken and documented and there are no contraindications to treatment with varenicline and any cautions to use have been considered and recorded (see Criteria for Exclusion and Referral)

3.	**Exclusion criteria**	• Pregnancy • End stage renal disease • Hypersensitivity to varenicline or any of the ingredients in the product • Children under 18 years old • Client not sufficiently motivated to quit • Varenicline should not be used with other pharmacotherapies for smoking cessation, i.e. Bupropion, nicotine replacement therapy (NRT) or nicotine containing vapes/e-cigarettes

4.	**Cautions / Need for further advice**	**Effect of smoking cessation** 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). As smoking induces CYP1A2, smoking cessation may result in an increase of plasma levels of CYP1A2 substrates. **Neuropsychiatric symptoms** Changes in behaviour or thinking, anxiety, psychosis, mood swings, aggressive behaviour, depression, suicidal ideation and behaviour and suicide attempts have been reported in patients attempting to quit smoking with varenicline in the post-marketing experience. A large randomised, double-blind, active and placebo-controlled study was conducted to compare the risk of serious neuropsychiatric events in patients with and without a history of psychiatric disorder treated for smoking cessation with varenicline, bupropion, nicotine replacement therapy patch (NRT) or placebo. The primary safety endpoint was a composite of neuropsychiatric adverse events that have been reported in post-marketing experience. Depressed mood, rarely including suicidal ideation and suicide attempt, may be a symptom of nicotine withdrawal. 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 primary endpoint compared with placebo 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.

4.	**Cautions / Need for further advice cont.,**	**History of psychiatric disorders** Smoking cessation, with or without pharmacotherapy, has been associated with exacerbation of underlying psychiatric illness (e.g. depression). Varenicline smoking cessation studies have provided data in patients with a history of psychiatric disorders In a smoking cessation clinical trial, neuropsychiatric adverse events were reported more frequently in patients with a history of psychiatric disorders compared to those without a history of psychiatric disorders, regardless of treatment. Care should be taken with patients with a history of psychiatric illness and patients should be advised accordingly. Patients should be advised to discontinue treatment and seek prompt medical advice if they develop agitation, depressed mood, or suicidal thoughts **Seizures** In clinical trials and post-marketing experience there have been reports of seizures in patients with or without a history of seizures, treated with varenicline. Varenicline should be used cautiously in patients with a history of seizures or other conditions that potentially lower the seizure threshold. Refer to BNF, under varenicline section, in particular the MHRA / CHM advice. **Cardiovascular events** 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.

4.	**Cautions / Need for further advice cont.,**	**Severe renal impairment (estimated creatinine clearance < 30 ml/min)** Reduced maximum dose 1mg once daily. **Breast-feeding** It is unknown whether varenicline is excreted in human breast milk. Animal studies suggest that varenicline is excreted in breast milk. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with varenicline should be made taking into account the benefit of breast-feeding to the child and the benefit of varenicline therapy to the woman. **Drug interactions** Based on varenicline characteristics and clinical experience to date, varenicline has no clinically meaningful drug interactions. It should be noted that the metabolism of some drugs will be affected if a patient stops smoking, as cigarette smoke interacts with some medicines by stimulating the cytochrome P450 enzymes (particularly CYP1A2). The drugs in which the interaction is of clinical importance are: erlotinib, flecainide, methadone, riluzole, riociguat, ropinirole, , theophylline warfarin and some antipsychotics including chlorpromazine, clozapine, and olanzapine. Patients should undergo appropriate medication review before stopping smoking if using any of these medications. For a full list of interactions refer to the appropriate reference sources, including UKMi_QA_Interactions with tobacco_update_Jul 2020, https://www.sps.nhs.uk/articles/what-are-the-clinically-significant-drug-interactions-with-tobacco-smoking/ the BNF and Stockley's Drug Interactions. Varenicline should not be used with other pharmacotherapies for smoking cessation, i.e. Bupropion,NRT or nicotine containing vapes/e-cigarettes.

5.	**Action if excluded**	Discuss alternative products if suitable i.e. Nicotine Replacement Therapies. An initial supply of two weeks of NRT can be supplied by the Pharmacist. The subsequent supplies of NRT may be issued by the Pharmacist if they are a trained Stop Smoking Practitioner (SSP) and are providing the behavioural support, or alternatively refer back to Smokefreelife Somerset for the direct supply of these products.
6.	**Action if patient declines or is excluded**	Refer the client to their GP for further assessment and advice.
7.	**When further Medical Advice should be sought**	**Cutaneous reactions** There have also been post-marketing reports of rare but severe cutaneous reactions, including Stevens-Johnson Syndrome and Erythema Multiforme in patients using varenicline. As these skin reactions can be life threatening, patients should discontinue treatment at the first sign of rash or skin reaction and contact a healthcare provider immediately. **Hypersensitivity reactions** There have been post-marketing reports of hypersensitivity reactions including angioedema in patients 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. Patients experiencing these symptoms should discontinue treatment with varenicline and contact a health care provider immediately. **Serious Neuropsychiatric symptoms** Patients should be advised to discontinue treatment and seek prompt medical advice if they develop agitation, depressed mood, or suicidal thoughts. At each contact pharmacists should actively enquire about any experience of these symptoms. Patients experiencing these symptoms should discontinue treatment with varenicline and contact a health care provider immediately.

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8.	Drug Details	
	Name, form and strength of medicine	Varenicline 500microgram tablets and 1mg tablets
	Legal Category	Prescription Only Medicine (POM)
	Black Triangle Status	No
	Route / method of administration	Oral
	Dosage	Days 1 - 3 : 500micrograms once a day Days 4 - 7 : 500micrograms twice a day Day 8 to end of treatment (up to 12 weeks in total) : 1mg twice a day Maximum single dose 1mg, maximum daily dose 2mg The client should set a date to stop smoking. Varenicline dosing should usually start 1 - 2 weeks before this date. Patients who cannot tolerate adverse reactions to varenicline may temporarily or permanently reduce their dose to 500micrograms twice daily. Days 1 - 3: 500micrograms once a day Days 4 to end of treatment: 500micrograms twice daily **Severe renal impairment (estimated creatinine clearance < 30 ml/min)** Reduced maximum dose 1mg once daily. Risk of relapse, irritability, depression and insomnia on discontinuation - dose tapering at end of course using a starter pack in reverse for weeks 11 and 12. Ensure the client has clear instructions to take the tablets in the starter pack in reverse.
	Frequency	Treatment to be provided every two weeks.

	Duration of treatment	Normally a maximum 12 weeks supply for any one quit attempt. However in exceptional circumstances where the client has successfully stopped smoking towards the end of 12 weeks, a further supply (maximum 12 weeks) can be supplied after discussion with the Pharmacist or SSP.
9.	**Side effects**	Smoking cessation with or without treatment is associated with various symptoms. For example: Irritability Dysphoric or depressed mood Frustration or anger Anxiety Restlessness Difficulty concentrating Increased appetite or weight gain Insomnia Decreased heart rate In clinical trials, in general, when adverse reactions occurred, onset was in the first week of therapy; and severity was generally mild to moderate. In clients treated with the recommended dose of varenicline 1mg twice a day following the initial titration period the adverse event most commonly reported was nausea (28.6%). In the majority of cases nausea occurred early in the treatment period, was mild to moderate in severity and seldom resulted in discontinuation.

9.	**Side effects cont.,**	If nausea is a problem for the patient their dose can be reduced to 500micrograms twice a day. **Very common side effects (≥ 1 in 10),** • Abnormal dreams, insomnia • Headache • Nausea • Nasopharyngitis **Common side effects (≥ 1 in 100 to <1 in 10)** • Weight increased, decreased appetite, increased appetite • Somnolence, dizziness, dysgeusia • Gastroesophageal reflux disease, vomiting, constipation, diarrhoea, abdominal distension, abdominal pain, toothache, dyspepsia, flatulence, dry mouth • Chest pain, fatigue • Bronchitis, sinusitis • Dyspnoea, cough • Rash, pruritus • Arthralgia, myalgia, back pain • Liver function test abnormal Refer to the Summary of product characteristics for uncommon and rare side effects
10.	**Reporting procedure of Adverse Reactions**	All adverse and suspected adverse reactions should be reported using the 'Yellow Card' reporting system, AND be reported to Smokefreelife Somerset, Somerset County Council Public Health. Nurses, pharmacists and the public can report adverse reactions to the CHM. This can be done by using a hard copy of a "Yellow Card" (available in the back of the BNF) or on-line via the website https://yellowcard.mhra.gov.uk/

11.	**Advice to patient / carer**	• Tablets should be swallowed whole with water and can be taken with or without food. • Where the patient is experiencing nausea they should be advised to take the tablets with a large glass of water after food. • The manufacturer's patient information leaflet (PIL) must be given to the client. • Varenicline may have minor or moderate influence on the ability to drive and use machines. Varenicline may cause dizziness and somnolence and therefore may influence the ability to drive and use machines. Clients should be advised not to drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether varenicline affects their ability to perform these activities. • Advise clients of possible side effects of smoking cessation and varenicline therapy. • Clients should be advised to discontinue treatment and seek prompt medical advice if they develop agitation, depressed mood, or suicidal thoughts. • Clients 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 a heart attack (myocardial infarction). • At the end of treatment, discontinuation of varenicline is associated with an increase in irritability, urge to smoke, depression, and/or insomnia in up to 3% of patients. The client should be advised of this, and the SSP should discuss or consider the need for dose tapering. • There have been post-marketing reports of hypersensitivity reactions including angioedema in patients 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. Patients experiencing these symptoms should discontinue treatment with varenicline and contact a health care provider immediately. • There have also been post-marketing reports of rare but severe cutaneous reactions, including Stevens-Johnson Syndrome and Erythema Multiforme in patients using varenicline. As these skin reactions can be life threatening, patients should discontinue treatment at the first sign of rash or skin reaction and contact a healthcare provider immediately. • Patients should be advised to discontinue treatment and seek prompt medical advice if they develop agitation, depressed mood, or suicidal thoughts.

12.	**Arrangements for follow up**	Client should be followed up at fortnightly intervals for the duration of their treatment.

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Referral Arrangements and Audit Trail		
13.	**Referral arrangements**	• Pharmacists should refer clients for varenicline, who are excluded from the PGD, to their GP If excluded from varenicline, the Pharmacist can supply the first two weeks of NRT, but the client should be referred back to Smokefreelife Somerset, Somerset County Council for direct supply of the remainder of the treatment if the Pharmacist is not a trained SSP

14.	**Record specific information for the supply/administration of medicines to include details for audit trail and significant events**	• Patient's name, address, date of birth and GP details; • Date supplied and name of the Clinician who supplied the medication; • Batch number and expiry date; • Reason for inclusion; • Advice given to patient; • Details of any adverse drug reaction and actions taken including documentation in the patient's medical record via GP. Following the last consultation, the Record of Supply Form and the original Client Assessment Form must be kept in the pharmacy for at least two years. All patient details should be recorded on the PharmOutcomes database.

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Staff Characteristics	
Professional qualifications	A pharmacist currently registered with the General Pharmaceutical Council.
Specialist competencies or qualifications	Training on the operation of this PGD by or on behalf of Smokefreelife Somerset, Somerset County Council
Continued education & training	Pharmacist will maintain clinical knowledge appropriate to their practice as part of their Continuing Professional Development.
Additional Requirements	If the Pharmacist is also providing the behavioural support to the client, they should be a trained Stop Smoking Practitioner, and on the National Centre for Smoking Cessation and Training (NCSCT) certified practitioner list.

References / Resources and comments

British National Formulary (BNF) online

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

https://www.gov.uk/drug-safety-update

National Institute for Health and Clinical Excellence (NICE)

- Varenicline for smoking cessation. NICE technology appraisal guidance (TA 123), July 2007
- Smoking cessation services. NICE Public Health Guidance 10. Last updated November 2013

Summary of Product Characteristics for Champix®. Pfizer Limited.

https://www.medicines.org.uk/emc/medicine/19045

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

The following PGDs were read as part of the development of this PGD:

Patient Group Direction (PGD) for the Supply of Varenicline (Champix®) by Authorised PGD Accredited Community Pharmacists working in Berkshire, 2014 – 2015. Bracknell Forest Council.

Patient Group Direction for the Supply of Varenicline (Champix®) by Smoking Cessation Advisers. Bromley Healthcare.

Patient Group Direction (PGD) for the Supply of Varenicline by Community Pharmacists. 6th March 2014. North Somerset Council and North Somerset CCG.

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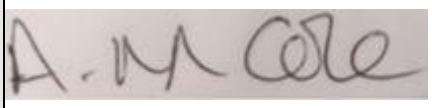
This patient group direction must be agreed to and signed by all health care professionals involved in its use. Somerset County Council should hold the original signed copy. The PGD must be easily accessible in the clinical setting	
Organisation	

Authorisation	**Signature**	**Date**
Nominated GP	Andrew Tresidder Dr Andrew Tresidder MBBS Cert Med Ed GMC 2823735	05/01/2023
Director of Public Health	 Prof Trudi Grant, MSc PH, UKPHR, FFPH Director of Public Health Somerset County Council	05/01/2023

Senior Pharmaceutical Advisor	 05/01/2023 Anne Cole, BPharm, MSc, FRPharmS
Consultant Microbiologist **(for Antibiotics)**	NA

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Individual Authorisation

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct.

Note to Authorising Managers: authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

I have read and understood the Patient Group Direction and agree to supply / administer this medicine only in accordance with this PGD.

PHARMACY:				
Name of Professional	**Professional registration no. (pharmacists only**	**Signature**	**Authorising Manager[1]**	**Date**

Please ensure a copy of this page is kept by the Line Manager

Pharmacists - Please return a copy to:

smokefreelife@somerset.co.uk

Smokefreelife Somerset, Public Health Department, Somerset County Council, County Hall, Taunton, TA1 4DY