

This Patient Group Direction (PGD) must only be used by Community Pharmacists who have been named and authorised by Parkwood Healthcare Limited to practice under it.

The most recent and in-date final authorised version of the PGD should be used.

Patient Group Direction (PGD)

for the

SUPPLY OF Varenicline Tablets 0.5mg and 1mg

BY ACCREDITED COMMUNITY PHARMACISTS for Smoking cessation in Rotherham (Who are approved by Parkwood Healthcare Limited – 'Approved Practitioners')


Version Number: v1.1 09/05/2018

Change history

Version number	Change details	Date
V1.0	New PGD for supply of Varenicline tablets	January 2018
V1.1	Updated – Initial feedback from LPC	9 th May 2018

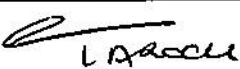
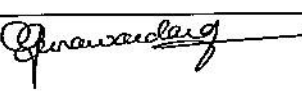

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PGD Development

Role / Name	Job Title and Organisation	Signature	Date
Lead Author	Vishal Mashru Pharmacist		16/5/18
Other members of the PGD working group	Nick Hunter – Chief Officer – Local Pharmacy Committee	N P Hunter	21 May.18
Other members of the PGD working group	Mark Lambourne – Managing Director – Parkwood Healthcare	Mark Lambourne	16/5/18

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PGD Authorisation

Role / Name	Job Title and Organisation	Signature	Date
Person signing on behalf of authorising body	Director Public Health RmBC		16.5.18
Clinical Sign Off	Dr Lihini Gunawardana Associate Medical Director (CGL)		16.05.18
Pharmacist Sign Off	Mohammed Fessal Chief Pharmacist(CGL)		16.05.18

Confirmation of PGD adoption by Pharmacy/Organisation

Role (*Delete as appropriate)	Pharmacy Branch name and address	Name of signatory	Signature	Date
Pharmacy manager/Superintendent/Area Manager				

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1. Training and competency of registered Community Pharmacist

	Requirements of registered Community Pharmacists working under the PGD
Qualifications and Professional Registration	Community Pharmacists registered with the General Pharmaceutical Council (GPhC)
Initial training	<p>Pharmacists must meet the standards required in the CPPE Declaration of Competence for Community Pharmacy Services – Stop smoking. This training is available online.</p> <p>Pharmacist must have completed CPPE Level 2 Safeguarding children and vulnerable adults. This training is available online.</p>
Competency Assessment	<p>Pharmacists must complete the CPPE “Declaration of Competence for Community Pharmacy Services – Stop smoking” every three years.</p> <p>Pharmacists will have appropriate indemnity insurance</p>
Ongoing Training and Competency	<p>Ongoing competency and training needs will be assessed by Parkwood Healthcare as part of the six monthly review of all providers working under PGDs.</p> <p>The Pharmacist is responsible for keeping up to date with the latest recommendations regarding smoking cessation, and undertaking regular CPD specific to this area of practise.</p> <p>Parkwood Healthcare will provide voluntary training on a local basis. These will be direct learning opportunities provided on an ad hoc basis to accommodate new suppliers covering:</p> <ul style="list-style-type: none"> • Clinical Knowledge • The PGD and the legalities of operating under a PGD • Where to get help and advice • The Service Specification • Documentation and record keeping • An opportunity to discuss and raise issues of concern of the pharmacists and their staff <p>This PGD will only apply whilst the pharmacist is commissioned to provide varenicline by Parkwood Healthcare as part of the lifestyle services specification.</p>

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2. Clinical condition or situation to which this Patient Group Direction applies

Clinical condition or situation to which this PGD applies	Clients accessing the Get Healthy Rotherham smoking cessation service who wish to access Varenicline as one of the treatment options.
Inclusion criteria	<ul style="list-style-type: none"> • Clients 18 years of age and over • Tobacco users identified as sufficiently motivated to quit • Tobacco users who are receiving support to stop smoking with the RMBC Integrated Lifestyle Service "Get Healthy Rotherham" • Client is a resident of Rotherham Borough • A medical history is taken and documented and there are no contraindications for treatment with Varenicline and that any cautions for use are recorded. Refer to <u>Appendix B</u> • No indication on PMR Summary Care Record that the patient is unsuitable for Varenicline
Exclusion criteria	<ul style="list-style-type: none"> • Tobacco users not sufficiently motivated to quit or use Varenicline • Clients under 18 years of age • Sensitivity to Varenicline or any of its excipients • Pregnancy/ Breastfeeding • Client already receiving Varenicline prescribed by GP • Renal impairment or end stage renal disease as decreased clearance by kidney increases side effects. (Use with caution in the elderly) • Epilepsy or history of fits or seizures • Clients who have experienced serious or worrying side effects from a previous course of varenicline • PMR indicates that patient is unsuitable for Varenicline • Clients with active or history of severe and enduring mental illness
Cautions (including any relevant actions to be taken)	<ul style="list-style-type: none"> • Patients with current or history of mild to moderate depression should be closely monitored and advised on the potential effects on mood and suicidal ideation and what to do should they experience any of these • If a client has diabetes or is taking theophylline/aminophylline or warfarin, ensure their GP is notified of their quit attempt/use of varenicline using the letter provided with this PGD. (<u>Appendix D</u>) • Patients on insulin may be supplied with Varenicline. However, patients should be advised to monitor their blood glucose level closely. • Patients taking warfarin, should advise the clinic of their intention to quit smoking using Varenicline when they next attend for a blood test • History of cardiovascular disease, monitor patient and advise on potential effects which include palpitations, tachycardia and increased in blood pressure • When the client stops smoking, metabolism of

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	theophylline is reduced which could cause plasma theophylline levels to rise, possibly to toxic levels if the dose of theophylline is not adjusted. <i>Signs of theophylline toxicity are: vomiting, dilated pupils, sinus tachycardia and hyperglycaemia</i>
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Action to be taken if patient is excluded	<p>1. If the patient is excluded from the PGD, but not excluded from being prescribed Varenicline i.e.</p> <ul style="list-style-type: none"> History of serious and enduring psychiatric illness – schizophrenia, bipolar, major depressive disorder Epilepsy <p>Pharmacists should refer clients back to Parkwood Healthcare for subsequent referral to an independent prescriber via PharmOutcomes for independent assessment as per the referral pathway.</p> <p>2. If patient is excluded for other reasons they should be referred back to Parkwood Healthcare via PharmOutcomes.</p>
Action to be taken if patient declines treatment	<ul style="list-style-type: none"> Refer back to Parkwood Healthcare via PharmOutcomes Record reasons for client refusal of treatment
Confidentiality	<p>A Pharmacists duty of confidentiality is outlined in the Medicines Ethics and Practice.</p> <p>Pharmacy users of all ages, including those who are under 16 years, providing that safeguarding issues have been addressed, are entitled to a confidential consultation with their pharmacist, although not all pharmacy users will be aware of this. Pharmacists may therefore consider advertising that all advisory services and consultations are confidential and that there is a consultation room available to discuss the matter privately.</p> <p>All practitioners and their supporting staff must respect their duty to confidentiality and information should not be disclosed to any third party without the clients consent.</p> <p>Pharmacists will manage and secure all sensitive data in line with their established policies and procedures as per the General Data Protection Regulation 2018.</p>

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3. Details of medicine and administration

Name, form and strength of medicine	Varenicline (Champix®) 0.5mg tablets Varenicline (Champix®) 1mg tablets
Legal category	POM
Route / method of administration	Oral
Indicate any off-label use (if relevant)	Not supported by PGD
Dose and frequency	<p>Days 1-3 500 micrograms (<i>white tablets</i>) once daily</p> <p>Days 4-7 500 micrograms twice daily</p> <p>Day 8 to end of treatment 1mg (<i>blue tablets</i>) twice daily for 11 weeks (Reduce to 500micrograms twice daily if not tolerated)</p> <p>Maximum single dose 1mg Maximum daily dose 2mg</p> <p>Clients should set a date to stop smoking. Client should start taking Varenicline 1-2 weeks before this date</p> <p>Tablets should be swallowed whole with plenty of water and can be taken with or without food</p> <p>Patients who cannot tolerate the adverse effects of Varenicline may have the dose lowered temporarily or permanently to 500 micrograms twice a day.</p> <p>Patients who are anxious about coming off Varenicline may have their dose lowered towards the end of treatment (maximum 12 weeks in total): Patients can be advised to taper their remaining tablets by taking one tablet daily for 3-4 days then one tablet every two days</p>
Quantity to be supplied	<ul style="list-style-type: none"> Clients should be supplied a 14-day initiation pack and should set a quit date 7 to 14 days after initiation (Clients should be seen weekly by their Stop Smoking Adviser for at least 4 weeks after the quit date, then fortnightly). At two weeks, pharmacists should receive confirmation from Parkwood Healthcare via PharmOutcomes that the patient has quit, and confirm that the clients GP has not objected to patient receiving Varenicline, then supply 2 weeks of Varenicline. All further supplies will be made at two weekly intervals after confirmation from Parkwood Healthcare that the

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	<p>client should continue on Varenicline.</p> <ul style="list-style-type: none"> Only 14-day prescription packs should be used throughout the quit attempt. A starter pack can be used in reverse for the final two weeks if appropriate. <p>The normal treatment course is up to 12 weeks</p>
Drug Interactions	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.
Side effects	<ul style="list-style-type: none"> Nausea Sleep disorders/abnormal dreams Headache Appetite changes Dry mouth/taste disturbances Drowsiness Dizziness <p>Please refer to SPC or current BNF (http://www.bnf.org.uk) for full details. Use the Yellow Card System to report adverse drug reactions directly to the CSM. Guidance on its use is available at the back of the BNF or can be accessed via the CSM website (http://www.yellowcard.gov.uk)</p>
Records to be kept	<p>Complete record of consultation for smoking cessation + Varenicline which includes;</p> <ul style="list-style-type: none"> Patients name, date of birth, postcode and consent given Name and address of GP Varenicline assessment form Dose and form administered/supplied Batch and expiry date details Communications with GP Advice given to patient (including side effects) Any ADR <p>Input data onto PharmOutcomes</p>

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4. Patient information

<p>Information to be given to the patient</p>	<ul style="list-style-type: none"> • Clients should be advised to set a quit date 7 to 14 days after initiation • Clients should be advised to discontinue Varenicline treatment immediately if they develop agitation, depressed moods, changes in their behaviour, or if they develop suicidal thoughts or behaviour ^[1] • 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 client 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 3. It does not remove all temptation to smoke, but it does make abstinence easier 4. Varenicline is safe, but about a third of clients may experience mild nausea some 30 minutes after taking it. This reaction usually diminishes gradually over the first few weeks, and most clients tolerate it without problems. If client is unable to tolerate due to nausea, consider dose reduction 5. Instruct on correct use and daily dose. Use mock product packaging for the explanation. Clients should take varenicline for 7 to 14 days before stopping smoking <p>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 clients. The pharmacist should inform the client accordingly and discuss or consider the need for dose tapering</p>
<p>Communication with clients general practice</p>	<p>In every case when the initial supply of Varenicline is made in accordance with this PGD, the pharmacist must inform the client's General Practitioner of the supply within two working days. <i>(Appendix D)</i></p>

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Appendix A: Health professionals' agreement to PGD

Authorised Pharmacists

- Must be currently registered with the GPhC and be practising as a Community Pharmacist.
- Must have completed the Declaration of Competence for Community Pharmacy Services – Stop smoking
- Must be named and confirmed as competent in the declaration below.

They should also:

- Undertake training updates at least every 2 years in line with CPPE recommendations.
- Be able to demonstrate CPD competence

Authorised individuals must not delegate their responsibility to another person

Record of Authorisation, Training and Competency Assessment of Community Pharmacist working under PGD for:

Supply of varenicline tablets 0.5mg and 1mg to selected clients

Name and details of Community Pharmacist authorised to work under this PGD

Name.....

Pharmacy name & address.....

	Details	Date
GPhC Registration number		
Relevant training completed		
Competency Assessment (DOC)		
Ongoing training and competency		

I confirm that I have read and understood the content of this patient group direction, I have received the appropriate training, and I am competent to implement it.

Signature..... Date.....

I (Line manager) on behalf
of..... (Insert organisation name) authorise the Pharmacist
named above to supply Varenicline under the terms of this patient group direction.

Signature..... Date.....

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Each community pharmacist authorised to use this PGD should retain a copy for their own records

Appendix B: Pharmacist's clinical assessment to supply Varenicline

Client name _____ DOB _____

Client address _____

To be utilised in conjunction with the Get Healthy Rotherham Integrated Lifestyle Service (Get Healthy Rotherham)

Is the client sufficiently motivated to stop smoking?

If answer is NO, **DO NOT** continue with this form or make a supply of Varenicline. Advise client to return when they feel they are ready to make a quit attempt.

Is the client taking any other medication? Client's taking medications that may be affected when they stop smoking should be advised to tell their GP of their quit attempt.

Yes / No (Please circle)

Names of medications patient is currently taking:

Criteria for exclusion

Criteria	Yes	No
Is the client sensitive to Varenicline tartrate or any of its excipients?		
Is the client under 18 years old?		
Does the client have end-stage renal disease?		
Is the client currently pregnant?		
Is the client breastfeeding?		
Does the client have epilepsy or history of fits or seizures or any conditions where seizure threshold may be lowered?		
Does the client have a history of serious psychiatric illness? (If yes, consider referring to appropriate service)		

If the client answers YES to any of the above then Varenicline may not be suitable. Other options that may be available to the client are:

- Refer back to Parkwood Healthcare (Get Healthy Rotherham)

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Appendix C: Not used

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Appendix D: Pharmacist notification to GP of supply of varenicline

URGENT & CONFIDENTIAL PHARMOUTCOMES NOTIFICATION

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.

Pharmacy stamp

GP Name _____

GP Practice address _____

Notification of supply of Varenicline

Client's name _____

Address _____

DOB _____ Contact number _____

Dear Dr _____

I write to advise you that your patient has been seen by me for smoking cessation treatment. They have expressed a wish to use Varenicline to aid their effort in stopping smoking, and a medical history has taken place to assess whether it is appropriate for them to receive it. 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 this local PGD. If you have any concerns about this person commencing Varenicline then please do not hesitate to contact me.

Strength and dosage of Varenicline given: _____

Pharmacist's name _____ Contact number _____

Signature _____ Date _____

Please note medical records may need updating if there is a change in the patients smoking status

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Appendix E: Pathway for stop smoking services

See separate attachment

Appendix F: Key contacts

Parkwood Healthcare

Mark Lambourne – Managing Director – mark.lambourne@parkwoodhealthcare.co.uk

Harpreet Sohal – Operations Manager – harpreet.sohal@parkwoodhealthcare.co.uk

Jacqui Reddick – Service Manager – jacqui.reddick@parkwoodhealthcare.co.uk

Rotherham Metropolitan Borough Council

Anne Charlesworth – Head of Public Health Commissioning – anne.charlesworth@rotherham.gov.uk

Sally Jenks – Public Health Specialist – sally.jenks@rotherham.gov.uk

Julie O'Neill – Contracts Officer (Public Health) – julie.o'neill@rotherham.gov.uk

Rotherham Local Pharmacy Committee

Nick Hunter – Chief Officer – nickhunter19@gmail.com

Pfizer

Rupert Brereton - Local Account Manager, Pfizer UK - rupert.brereton@pfizer.com

PharmOutcomes

Esther Harvey – PharmOutcomes - esther.harvey@phpartnership.com

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References

1. British National Formulary Edition 74
2. NICE TA 123: <https://www.nice.org.uk/Guidance/TA123> [Last accessed 21/2/18]
3. SPC for varenicline: <https://www.medicines.org.uk/emc/search?q=varenicline> [Last accessed 20/2/18]
4. MHRA Safety Alert: <https://www.gov.uk/drug-safety-update/varenicline-and-suicidal-behaviour-cohort-study-provides-some-reassurance> [Last accessed 18/2/18]
5. Worcestershire Smoking Cessation Pharmacotherapy guideline: <http://www.worcestershire.nhs.uk/EasySiteWeb/GatewayLink.aspx?alld=5468> [Last accessed 26/2/18]

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