



## PATIENT GROUP DIRECTION

Supply of varenicline 0.5mg and 1mg film coated tablets  
by registered pharmacists for smoking cessation in  
community pharmacy

Version 4.0

Valid from: 11/01/2022

Expires on: 10/01/2024

This Patient Group Direction (PGD) must only be used by registered health professionals 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.

<b>Varenicline 0.5mg and 1mg Film Coated Tablets</b>	<b>P.O.M.</b> [Prescription Only Medicine]
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**DOCUMENT CONTROL – PGD Ready for authorisation**

**Document Location**

Copies of this PGD can be obtained from:

<b>Name:</b>	Rochdale Metropolitan Borough Council
<b>Address:</b>	No. 1 Riverside, Smith Street, Rochdale OL16 1XU
<b>Telephone:</b>	01706 652888

**Revision History**

The latest and master version of the unsigned PGD is held by Greater Manchester Joint Commissioning Team.

Revision date & Actioned by	Summary of Changes	Version				
13/12/2017 S Woods	Final formatting for sign off.	2.0				
27/11/2019 S Woods	Final formatting for printing.	3.0				
18/11/2020 K Osowska	Amendments made after commissioner request and as per service specification.	3.1				
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 30%;">PGD section</th> <th>Changes made</th> </tr> <tr> <td>Indication (Clinical condition or situation to which this PGD applies)</td> <td>                     Addition of the second bullet point:                     <ul style="list-style-type: none"> <li>Receiving specialist advice and support from a pharmacy commissioned by Rochdale’s stop smoking service, who have expressed a desire to quit smoking and for whom varenicline has been assessed as a suitable treatment option</li> </ul> </td> </tr> </table>		PGD section	Changes made	Indication (Clinical condition or situation to which this PGD applies)	Addition of the second bullet point: <ul style="list-style-type: none"> <li>Receiving specialist advice and support from a pharmacy commissioned by Rochdale’s stop smoking service, who have expressed a desire to quit smoking and for whom varenicline has been assessed as a suitable treatment option</li> </ul>
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18/11/2020 K Osowska	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 30%;">Criteria for inclusion</th> <td>                     Replacing bullet point                     <ul style="list-style-type: none"> <li>A full medical history has been taken and documented</li> </ul>                     with bullet point                     <ul style="list-style-type: none"> <li>Patient’s medical history has been checked against the inclusion and exclusion criteria and patient is deemed to be eligible to be treated under this PGD’</li> </ul> </td> </tr> <tr> <th>Criteria for exclusion</th> <td>Bullet point ‘no initial referral letter or confirmation letter of ongoing support’ amended to ‘if referred by the Rochdale’s stop smoking team, no initial referral letter or confirmation letter of ongoing support</td> </tr> </table>	Criteria for inclusion	Replacing bullet point <ul style="list-style-type: none"> <li>A full medical history has been taken and documented</li> </ul> with bullet point <ul style="list-style-type: none"> <li>Patient’s medical history has been checked against the inclusion and exclusion criteria and patient is deemed to be eligible to be treated under this PGD’</li> </ul>	Criteria for exclusion	Bullet point ‘no initial referral letter or confirmation letter of ongoing support’ amended to ‘if referred by the Rochdale’s stop smoking team, no initial referral letter or confirmation letter of ongoing support	3.1
	Criteria for inclusion	Replacing bullet point <ul style="list-style-type: none"> <li>A full medical history has been taken and documented</li> </ul> with bullet point <ul style="list-style-type: none"> <li>Patient’s medical history has been checked against the inclusion and exclusion criteria and patient is deemed to be eligible to be treated under this PGD’</li> </ul>				
Criteria for exclusion	Bullet point ‘no initial referral letter or confirmation letter of ongoing support’ amended to ‘if referred by the Rochdale’s stop smoking team, no initial referral letter or confirmation letter of ongoing support					

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	Presentation	<p>'Titration pack' amended to 'treatment initiation pack'</p>	
	Quantity to be administered and/or supplied	<p>Quantity was amended from 3 supplies to 4 supplies as following:</p> <p>1<sup>st</sup> supply -2 weeks</p> <p>2<sup>nd</sup> supply – 4 weeks</p> <p>3<sup>rd</sup> supply- 4 weeks</p> <p>4<sup>th</sup> supply – 2 weeks</p>	
		<p>Addition of the note reflecting on the provision of the service during COVID 19 pandemic:</p> <p>'The service is usually delivered face to face at the pharmacy premises. For the duration of the COVID-19 pandemic, to reduce risk of transmission, pharmacists may use their professional judgement on how they provide smoking cessation service. E.g., Remotely via telephone or appropriate digital methods. If the service is to be delivered remotely, the pharmacist must ensure that an appropriate consultation/clinical review takes place and the patient is seen face to face if required. Remote consultations must be conducted in a manner that ensures necessary patient confidentiality. If the service is provided remotely, products must be supplied in a timely fashion. Supplies made utilising this temporary adjustment should be recorded as such.'</p>	
18/11/2020 K Osowska	Appendix 2	<ul style="list-style-type: none"> <li>• Addition of the note reflecting on recording the consultation during COVID19 pandemic</li> <li>• Removal of the requirement of obtaining written consent from the patient.</li> </ul> <p>It was confirmed with GM LPC that there is no requirement to obtain written consent from the patient under this PGD in any circumstances. Patients give consent to participate in the service which is recorded in PharmOutcomes and the patient assessment form is also recorded in PharmOutcomes.</p>	3.1
	Advice to be given to the patient or carer	<p>Last bullet point amended to reflect on removal of the requirement of obtaining written consent from the patient participating in the service.</p>	

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		<ul style="list-style-type: none"> <li>Information obtained in this consultation will be shared with their GP and Rochdale's stop smoking services and they must consent to this (obtain written consent) in order to access this service.</li> </ul> <p>Changed to:</p> <ul style="list-style-type: none"> <li>Information obtained in this consultation will be shared with their GP and Rochdale's stop smoking services and they must consent to this in order to access the service.</li> </ul>	
18/12/2020 K Osowska	Criteria for exclusion	Removed bullet point: 'patients drinking more than 21 units of alcohol per week' as there is no evidence to support that statement.	3.2
		Addition of bullet point: 'patients with schizophrenia or schizoaffective disorder'	
	Advice to be given to the patient or carer	Addition of advice on alcohol effects on people taking varenicline.	
	References	Addition of 2 new references on effect of alcohol on patients taking varenicline	
	Appendix 1	Statement 'Those clients that drink excessively (>21 units of alcohol per week) may benefit from referral to other services for support to reduce their drinking in the first instance. Alternatively consider the use of NRT in these clients', changed to 'Those clients that drink excessively may benefit from referral to other services for support to reduce their alcohol drinking.'	
18/12/2020 K Osowska	Appendix 1	Addition of statement: 'Patients with schizophrenia or schizoaffective disorder should be advised that the evidence for the use of varenicline is not sufficiently clear to allow its use in this patient group'.	3.2
	Appendix 2	Client assessment form was amended along the updated exclusion criteria.	
19/09/2021 K Osowska	Suggested supporting learning	Recommendation changed to reflect the Rochdale Pharmacy Smoking Cessation Service Specification.	3.3

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	Criteria for inclusion	<ul style="list-style-type: none"> <li>▪ 1<sup>st</sup> bullet point amended to ‘Tobacco users identified as sufficiently motivated to quit (willing to set a quit date between 1-2 weeks of starting treatment) and receive motivational support through face-to-face visits, phone calls or texts for the first four weeks at least’</li> <li>▪ 5<sup>th</sup> bullet point amended to ‘There are no known allergies or contraindications to varenicline or the excipients’</li> </ul>	
	Criteria for exclusion	Addition of new bullet point: Patients who take cimetidine	
19.09.2021 K Osowska	Cautions (including any relevant action to be taken)	<p>Addition of two new bullet points:</p> <ul style="list-style-type: none"> <li>▪ Patients should be monitored at each collection point for neuropsychiatric symptoms, in particular those with a history of or currently being treated for psychiatric illness. Psychiatric patients receiving treatment for their psychiatric illness should be advised to let the healthcare professional responsible for their care know that they are receiving varenicline</li> <li>▪ Smoking cigarettes (not the nicotine) may alter the metabolism of some medicines by stimulating the hepatic enzymes including CYP1A2. When smoking is stopped, the dose of these drugs may need to be adjusted, and the person monitored regularly for adverse effects. For more information, please see NICE CKS and the SPS UKMi.</li> </ul>	3.3
	Dose and frequency	Removal of the statement as there is no reference provided and can cause confusion: ‘Patients may decide to discontinue treatment before the end of the 12 week period but they should be advised that the continuous abstinence rate is higher for those that continue treatment for weeks 9 through 12’.	3.3
	Unlicensed/off label use	Removal of the statement ‘Use of varenicline for <12 weeks is an off-label use’. This PGD does not recommend ‘off label’ use of varenicline.	
	Maximum or minimum treatment periods	Addition of 3 bullet points (to reflect the Service Specification) and removal of the	

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		statement that varenicline can only be supplied for 12 weeks under this PGD.	
19.09.2021 K Osowska	Records	Addition of the statement (to reflect the Service Specification): The pharmacist must make an entry for each patient on the PharmOutcomes system and complete all mandatory entries as required by the service specification and this PGD.	3.3
		Amendments on required records as per Specialist Pharmacy Service, PGD template, March 2021	
	Advice to be given to the patient or carer	Addition of 3 new bullet points: <ul style="list-style-type: none"> <li>▪ Patients taking theophylline should be advised to seek medical help if they develop signs of theophylline toxicity such as palpitations or nausea</li> <li>▪ Information that varenicline may have minor or moderate influence on their ability to drive and use machines. Varenicline may cause dizziness and somnolence and therefore may influence the ability to drive and use machines. Patients are advised not to drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether this medicinal product affects their ability to perform these activities</li> <li>▪ Patients taking methadone should be advised to alert for signs of opioid toxicity</li> </ul>	
	References used to develop this PGD	All references updated	
	Individual authorisation	This form was replaced with Pharmacist authorisation sheet as per Specialist Pharmacy Service, PGD template, March 2021	
	Appendix 2	Addition of Q9	
24.09.2021 K Osowska	Name, strength & formulation of drug	Champix® is probably very soon coming off the patent therefore brand name was removed to enable dispensing other brands when available.	
	Whole document	Champix® is probably very soon coming off the patent therefore brand name was	

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		removed (where applicable) to enable dispensing other brands when available.	
21.10.2021 K Osowska	Criteria for exclusion	<p>Removal of the statement: ‘Use of varenicline or bupropion within the last 3 months (except where a patient suffered an adverse drug reaction to bupropion and had to stop treatment early).</p> <p>No evidence found (including current Service Specification) to support the statement. It has no clinical meaning as there are no restrictions to varenicline retreatments and varenicline and bupropion.</p>	3.3
	Appendix 2	<p>Question ‘Have you used varenicline or bupropion within the last 3 months?’ removed as there was no evidence found to support it. No information on limitations around retreatment with varenicline within the Service Specification either.</p>	
19.11.2021 K Osowska	Final formatting for sign off.		4.0

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**Approvals**

This PGD must be approved by the following before distribution:

NAME	TITLE	DATE OF ISSUE	VERSION
Dr Aggy York	Clinical Lead Heywood, Middleton & Rochdale CCG	30.11.2021	4.0
Andrew Martin	Strategic Medicines Optimisation Pharmacist, GM Joint Commissioning Team	19.11.2021	4.0
Kuiama Thompson	Director of Public Health, Rochdale Metropolitan Borough Council		4.0
Luvjit Kandula	Director of Pharmacy Transformation GM LPC	23.11.2021	4.0

**Distribution**

This PGD has been distributed to during its development:

NAME	TITLE	DATE OF ISSUE	VERSION
Dr Aggy York	Clinical Lead Heywood, Middleton & Rochdale CCG	21.10.2021 19.11.2021	3.1 4.0
Luvjit Kandula	Director of Pharmacy Transformation GM LPC	21.10.2021 19.11.2021	3.1 4.0
Andrew Martin	Strategic Medicines Optimisation Pharmacist, GM Joint Commissioning Team	21.10.2021 19.11.2021	3.1 4.0

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**PGD Development**

<b>Originally developed / Reviewed by:</b>	Stephen Woods (author)	Senior Medicines Optimisation Pharmacist, Greater Manchester Joint Commissioning Team
	Karina Osowska (reviewer)	Advanced Medicines Optimisation Pharmacist, Greater Manchester Joint Commissioning Team
	Dr Aggy York	Clinical Lead Heywood, Middleton & Rochdale CCG
	Luvjit Kandula	Director of Pharmacy Transformation GM LPC
	Dr Keith Pearson	Head of Medicines Optimisation, Heywood, Middleton & Rochdale CCG

<b>Date applicable:</b>	11/01/2022
<b>Review date:</b>	01/08/2023
<b>Expiry date:</b>	10/01/2024

**PGD Authorisation**

This Patient Group Direction has been approved for use in the Rochdale Metropolitan Borough Council area by:

Designation	Name	Signature	Date
Senior Pharmacist (Strategic Medicines Optimisation Pharmacist, GMJCT)	Andrew Martin		19.11.2021
Doctor (Clinical Lead Heywood, Middleton & Rochdale CCG)	Dr Aggy York		30.11.2021
Pharmacist Representative (Director of Pharmacy Transformation GM LPC)	Luvjit Kandula		23.11.2021
Pharmacist Reviewer (Advanced Medicines Optimisation Pharmacist GMJCT)	Karina Osowska		19.11.2021

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<b>Authorised Signatory for Rochdale Metropolitan Borough Council (Director of Public Health)</b>	Kuiama Thompson		10/12/21
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**1. Characteristics of Staff**

<b>Qualifications required</b>	<ul style="list-style-type: none"> <li>▪ Pharmacist with a current General Pharmaceutical Council registration</li> <li>▪ Work in a Community Pharmacy within Rochdale Metropolitan Borough Council area.</li> </ul>
<b>Additional requirements</b>	<ul style="list-style-type: none"> <li>▪ Has undertaken training in the use of PGDs                             <ul style="list-style-type: none"> <li>▪ Has undertaken and successfully completed training which enables the pharmacist to make a clinical assessment in order to establish the need for and supply the treatment according to this PGD and as detailed in the service specification.</li> </ul> </li> <li>▪ Has completed and satisfied the competencies appropriate to this PGD, as detailed in the CPPE Declaration of Competence for pharmacy services – Smoking Cessation Intervention Service:                             <ul style="list-style-type: none"> <li>♦ <i>Stop smoking advisor</i></li> <li>♦ <i>Pharmacist supply of Prescription Only Medicines via PGD document.</i></li> </ul>                             Available here: <a href="https://www.cppe.ac.uk/services/declaration-of-competence#navTop">https://www.cppe.ac.uk/services/declaration-of-competence#navTop</a>.                         </li> <li>▪ Is competent in the assessment of the individuals using Fraser guidelines</li> </ul>
<b>Continued training requirements</b>	<ul style="list-style-type: none"> <li>▪ The pharmacist should be aware of any change to the recommendations for the medicine listed.</li> <li>▪ Must be able to show regular update in the field of smoking cessation services and their delivery.</li> <li>▪ Must assess and maintain their own competence annually on the medicine supplied under this PGD in line with the requirements contained within the <i>Declaration of Competence for pharmacy services – Smoking Cessation Intervention Service</i>:                             <ul style="list-style-type: none"> <li>♦ <i>Stop smoking advisor</i></li> <li>♦ <i>Pharmacist supply of Prescription Only Medicines via PGD document.</i></li> </ul> </li> <li>▪ It is the responsibility of the pharmacist to keep up to date with continuing professional development.</li> <li>▪ It is the responsibility of the pharmacist to maintain their own competency to practice within this PGD. Further training may be necessary when the PGD is reviewed.</li> </ul>
<b>Suggested supporting learning</b>	All supporting learning/training recommended by the Rochdale Pharmacy Smoking Cessation Service Specification.

**The Pharmacy Contractor is responsible for ensuring that only suitable Pharmacists sign up to this PGD and should maintain a record of the names of individual Pharmacists and evidence of their self-declaration and sign up to the current PGD.**

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**2. Clinical condition or situation to which the direction applies.**

<b>Indication (Clinical condition or situation to which this PGD applies)</b>	Provision of varenicline to tobacco users who are: <ul style="list-style-type: none"> <li>▪ Receiving specialist advice and support from the Rochdale’s stop smoking service and in possession of an initial referral letter or confirmation letter of ongoing support</li> <li>▪ Receiving specialist advice and support from a pharmacy commissioned by Rochdale’s stop smoking service, who have expressed a desire to quit smoking and for whom varenicline has been assessed as a suitable treatment option</li> </ul>
<b>Criteria for inclusion</b>	<ul style="list-style-type: none"> <li>▪ Tobacco users identified as sufficiently motivated to quit (willing to set a quit date between 1-2 weeks of starting treatment) and receive motivational support through face to face visits, phone calls or texts for the first four weeks at least</li> <li>▪ Patients aged 18 years or over</li> <li>▪ Consent has been obtained and recorded</li> <li>▪ Patient’s medical history has been checked against the inclusion and exclusion criteria and patient is deemed to be eligible to be treated under this PGD</li> <li>▪ There are no known allergies or contraindications to varenicline or the excipients</li> <li>▪ Completion of client assessment form (see appendix 2) in conjunction with the client assessment form guidance (appendix 1) Varenicline should be considered as an option for use (when used as part of a managed programme)</li> </ul>
<b>Criteria for exclusion<sup>1</sup></b>	<ul style="list-style-type: none"> <li>▪ No valid consent to share information with their GP and Rochdale’s stop smoking services</li> <li>▪ If referred by the Rochdale’s stop smoking team, no initial referral letter or confirmation letter of ongoing support</li> <li>▪ Use with other smoking cessation therapies</li> <li>▪ Tobacco users who are not sufficiently motivated to quit or use varenicline</li> <li>▪ Patients under the age of 18 years</li> <li>▪ Pregnant or breastfeeding mothers</li> <li>▪ Hypersensitive to varenicline or any of the excipients</li> <li>▪ Patients who take cimetidine</li> <li>▪ Known renal impairment</li> <li>▪ Unstable cardiovascular disease (e.g., angina)</li> <li>▪ All patients who have answered ‘Yes’ to any question on the client assessment form</li> <li>▪ Patients with epilepsy or a history of seizures</li> <li>▪ Patients with schizophrenia or schizoaffective disorder</li> </ul>

<sup>1</sup> Exclusion under this Patient Group Direction (PGD) does not necessarily mean the medication is contraindicated but it may be outside the remit of the PGD and patient could be referred to an independent prescriber for further assessment.

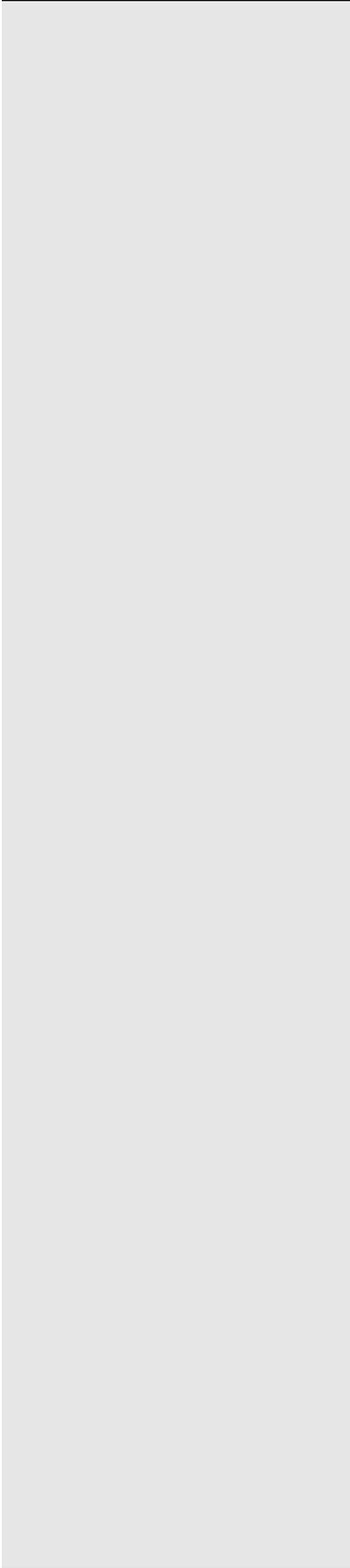
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**Cautions (including any relevant action to be taken)**

**Continued on next page**

- **Cardiovascular events:**
  - ◆ In a trial of patients with stable cardiovascular disease (CVD) certain cardiovascular events were reported more frequently in patients treated with varenicline. A meta-analysis of 15 clinical trials, which included the smoking cessation trial of patients with stable CVD, had similar results.
  - ◆ 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.
- **History of psychiatric disorder:**
  - ◆ Smoking cessation, with or without pharmacotherapy, has been associated with exacerbation of underlying psychiatric illness (e.g., depression).
  - ◆ Champix® 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 to discontinue varenicline immediately and contact a healthcare professional for re-evaluation of treatment if neuropsychiatric symptoms occur whilst on treatment.
- **Neuropsychiatric symptoms:**
  - ◆ Depressed mood, rarely including suicidal ideation and suicide attempt, may be a symptom of nicotine withdrawal.
  - ◆ 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.
  - ◆ Patients should be monitored at each collection point for neuropsychiatric symptoms, in particular those with a history of or currently being treated for psychiatric illness. Psychiatric patients receiving treatment for their psychiatric illness should be advised to let the healthcare professional responsible for their care know that they are receiving varenicline
- **Cautions relevant to all smoking cessation attempts, not specific to using varenicline:**
  - ◆ Smoking cigarettes (not the nicotine) may alter the metabolism of some medicines by stimulating the hepatic enzymes including

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CYP1A2. When smoking is stopped, the dose of these drugs may need to be adjusted, and the person monitored regularly for adverse effects. For more information please see [NICE CKS](#) and the [SPS UKMi](#) .

- ◆ Theophylline is metabolised in the liver via CYP1A2, 2E1 and 3A3. Smokers need higher doses of theophylline than non-smokers due to theophylline’s shortened half-life and increased clearance. Some reports suggest when stopping smoking a reduction in theophylline dose up to 25-33% might be needed after one week. Therefore, stopping smoking may have a clinical relevance and patients should be advised to seek help if they develop signs of theophylline toxicity such as palpitations or nausea.
- ◆ Warfarin is partly metabolised via CYP1A2 and 2C9. If a person taking warfarin stops smoking, their INR might increase so monitor the INR more closely. Advise people to tell the healthcare professional managing their anticoagulant control that they are stopping smoking
- ◆ Methadone is metabolised in liver via numerous isoenzymes including CYP1A2. There has been a case report of respiratory insufficiency and altered mental status when a patient taking methadone for analgesia stopped smoking. Advise the patient to be alert for signs of opioid toxicity.
- ◆ In diabetic patients there is some evidence to suggest that until the body readjusts after the withdrawal of nicotine, glycaemic control may be affected and therefore patients need to be extra vigilant and may need closer monitoring through this period.

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<b>Action if excluded</b>	<ul style="list-style-type: none"> <li>▪ Consider other forms of smoking cessation therapy i.e., Nicotine Replacement Therapy (NRT).</li> <li>▪ Refer to Rochdale’s stop smoking service for further support or to their GP for further assessment where available</li> </ul>
<b>Action if patient or carer declines treatment</b>	<ul style="list-style-type: none"> <li>▪ Inform patient regarding risks of not receiving treatment compared to the benefits.</li> <li>▪ Consider other forms of smoking cessation therapy i.e., Nicotine Replacement Therapy (NRT).</li> <li>▪ Refer to Rochdale’s stop smoking service for further support or to their GP for further assessment where available</li> </ul>

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**P.O.M.**  
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**3. Details of medicine**

<b>Name, strength &amp; formulation of drug</b>	0.5mg film-coated tablets and 1mg film-coated tablets containing 0.5mg or 1mg of varenicline (as tartrate).
<b>Presentation</b>	<ul style="list-style-type: none"> <li>▪ 0.5mg 56-tablets pack</li> <li>▪ 1 mg 28-tablets pack &amp; 56-tablets pack</li> <li>▪ Treatment initiation pack of 11 x 0.5mg tablets with 14 x 1mg tablets</li> </ul>
<b>Legal category</b>	POM
<b>Black Triangle ▼</b>	No
<b>Unlicensed / off label use</b>	None
<b>Route / method</b>	<ul style="list-style-type: none"> <li>▪ Oral administration.</li> <li>▪ Swallow tablets whole with water.</li> <li>▪ Take with or without food.</li> </ul>
<b>Dose and frequency</b>	<p>Smokers set a date to stop smoking and treatment with varenicline should start 1 to 2 weeks before this date.</p> <p>The recommended dose is varenicline 1mg twice daily following a 1-week titration as follows:</p> <ul style="list-style-type: none"> <li>▪ Days 1-3:             <ul style="list-style-type: none"> <li>◆ 0.5mg once daily</li> </ul> </li> <li>▪ Days 4-7:             <ul style="list-style-type: none"> <li>◆ 0.5mg twice daily</li> </ul> </li> <li>▪ Day 8 – end of treatment (12 weeks in total):             <ul style="list-style-type: none"> <li>◆ 1mg twice daily</li> </ul> </li> </ul> <p>Patients who cannot tolerate adverse reactions of varenicline on 1mg twice daily may have the dose lowered temporarily or permanently to 0.5 mg twice daily.</p>

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<b>Quantity to be administered and/or supplied</b>	<p>1<sup>st</sup> supply - 2 weeks (Treatment initiation pack – see 'Presentation')</p> <p>2<sup>nd</sup> supply - 4weeks</p> <p>3<sup>rd</sup> supply - 4 weeks</p> <p>4<sup>th</sup> supply - 2 weeks</p> <ul style="list-style-type: none"> <li>▪ Patients who would normally pay for prescription charges should be charged at the standard prescription tariff. If the patient receives other medication it may be appropriate to consider a Prescription Pre-Payment Certificate.</li> <li>▪ Labelling requirements: Products must be labelled in accordance with the requirement of the <a href="#">Medicines for Human Use Regulations 1994</a></li> </ul> <p><b>Note reflecting on provision of the service during COVID 19 pandemic:</b></p> <p>The service is usually delivered face to face at the pharmacy premises. For the duration of the COVID-19 pandemic, to reduce risk of transmission, pharmacists may use their professional judgement on how they provide smoking cessation service (e.g., remotely via telephone or appropriate digital methods). If the service is to be delivered remotely, the pharmacist must ensure that an appropriate consultation/clinical review takes place and the patient is seen face to face if required. Remote consultations must be conducted in a manner that ensures patient confidentiality. If the service is provided remotely, products must be supplied in a timely fashion. Supplies made utilising this temporary adjustment should be recorded as such.</p>
<b>Maximum or minimum treatment periods</b>	<ul style="list-style-type: none"> <li>▪ After suitable review, on rare occasions, patients that have successfully stopped smoking at the end of the initial 12 weeks treatment may warrant an additional course of 12 weeks treatment at 1mg (0.5mg if higher dose not previously tolerated) twice daily.</li> <li>▪ Any rationale for additional treatment beyond the initial 12 weeks should be documented in the patient's consultation documentation.</li> <li>▪ Patients should not receive more than 24 weeks treatment in total.</li> </ul>
<b>Drug interactions<sup>2</sup></b>	<ul style="list-style-type: none"> <li>▪ If the patient is taking any concomitant medication or treatment, it is the pharmacist's responsibility to ensure that treatment with the drug detailed in this PGD is appropriate. For drug interaction see <a href="#">BNF</a> online or contact the <a href="#">UKMi Medicine Information at Liverpool</a></li> <li>▪ In case of any doubt, further advice must be sought from an appropriate healthcare professional and recorded as having been sought before the drug is given.</li> <li>▪ If the requirements of this Patient Group Direction cannot be complied with the patient must be referred to a suitable independent prescriber.</li> </ul>

<sup>2</sup> Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list

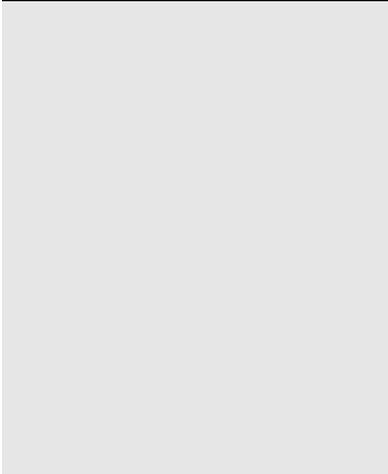
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<b>Identification &amp; management of adverse reactions<sup>2</sup></b>	<p>It is important to note that smoking cessation is often associated with nicotine withdrawal symptoms (agitation, insomnia, tremor, sweating) some of which are also recognised side effects of varenicline.</p> <p>Varenicline adverse reactions:</p> <ul style="list-style-type: none"> <li>▪ <b>Very common (&gt; 1/10)</b></li> </ul> <p>Nasopharyngitis, headache, abnormal dreams, insomnia, nausea.</p> <ul style="list-style-type: none"> <li>▪ <b>Common (&gt;1/100 to &lt;1/10)</b></li> </ul> <p>Bronchitis, sinusitis, weight increased, decreased appetite, increased appetite, somnolence, dizziness, dysgeusia, dyspnoea, cough, gastroesophageal reflux disease, vomiting, constipation, diarrhoea, abdominal distension, abdominal pain, toothache, dyspepsia, flatulence, dry mouth, rash, pruritus, arthralgia, myalgia, back pain, chest pain, fatigue, liver function test abnormal.</p> <ul style="list-style-type: none"> <li>▪ <b>For uncommon (<math>\geq 1/1,000</math> to <math>&lt; 1/100</math>) and rare (<math>\geq 1/10,000</math> to <math>&lt; 1/1,000</math>) adverse reactions see <a href="#">SmPC</a> or <a href="#">BNF</a></b></li> </ul> <p>When necessary adverse reactions should be reported using the <a href="#">Yellow Card system</a></p>
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## 4. Records

<b>Records</b>	<p>The pharmacist must make an entry for each patient on the PharmOutcomes system and complete all mandatory entries as required by the service specification and this PGD</p> <p>The following should be recorded as a minimum:</p> <ul style="list-style-type: none"> <li>♦ Patient’s name, address, date of birth</li> <li>♦ Contact details of GP (if registered)</li> <li>♦ Any known allergies and nature of reaction</li> <li>♦ Relevant past and present medical history</li> <li>♦ Name of the medication</li> <li>♦ Dose and date of supply</li> <li>♦ Quantity, batch number and expiry date</li> <li>♦ Name of pharmacist who supplied the medicine.</li> <li>♦ Advice given to the patient.</li> <li>♦ Advice given if excluded or declines treatment.</li> <li>♦ Details of any adverse drug reaction and action taken</li> <li>♦ Record of any follow up or referrals</li> <li>♦ Prescription charges collected</li> <li>♦ Consent to share information with patient’s GP and Rochdale Stop Smoking Service</li> </ul> <ul style="list-style-type: none"> <li>▪ Patient’s GP should be informed that the patient has been supplied with varenicline within 2 working days from the date of issue (or in the case of weekends and bank holidays the next working day).</li> </ul>
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- Data must be stored in accordance with Caldicott guidance and the Data Protection Act and the General Data Protection Regulation.
- All records should be clear, legible, and contemporaneous.
- Records of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes.

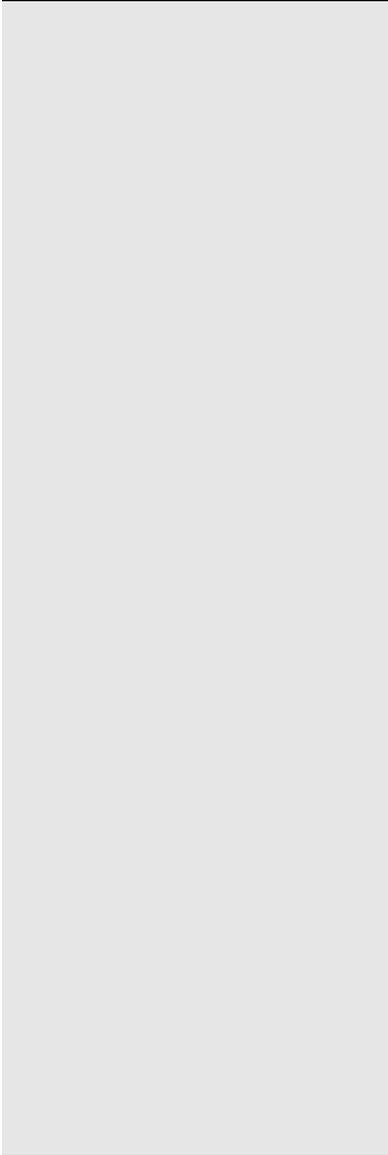
*As per SPS Retention of Pharmacy Record and SPS Retaining PGD documentation:*

PGD records should be stored for adults aged 18 years and over for 8 years and for children until the 26th birthday or for 8 years after a child's death.

**5. Patient Information**

<b>Written information to be given to the patient or carer</b>	<p>The patient should be given following written information if appropriate:</p> <ul style="list-style-type: none"> <li>▪ The product specific patient information leaflet supplied with the medicine.</li> <li>▪ Any other suitable information regarding their treatment and services available.</li> </ul>
<b>Advice to be given to the patient or carer</b>	<p>Patients should be given the following information verbally if appropriate:</p> <ul style="list-style-type: none"> <li>▪ Information on using the treatment initiation pack at the first supply.</li> <li>▪ Information on possible side effects and their management.</li> <li>▪ Advise of the possible emergence of depressive symptomatology when attempting to stop smoking.</li> <li>▪ Advise of the need to discontinue treatment at the first sign of a rash or skin reaction and to seek medical advice immediately.</li> <li>▪ Information of the need to discontinue treatment and to seek medical advice immediately if any of the following clinical signs occur:                         <ul style="list-style-type: none"> <li>◆ swelling of the face, mouth (tongue, lips and gums)</li> <li>◆ neck (throat and larynx)</li> <li>◆ extremities and/or</li> <li>◆ difficulty breathing</li> </ul> </li> <li>▪ Information to seek medical advice should other symptoms develop after treatment has started</li> <li>▪ Advise that varenicline can change the way people react to alcohol, decrease tolerance, increase drunkenness and cause aggressive behaviour and no memory events. Until patients know how varenicline affects their ability to tolerate alcohol, they should decrease the amount of alcohol they drink</li> <li>▪ Diabetic insulin-dependent patients should be advised to be extra vigilant for symptoms of hypoglycaemia and to monitor their blood glucose more frequently</li> </ul>

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- Patients taking warfarin should be advised to inform their anticoagulant clinic or whoever monitors their INR that they are stopping smoking
- Patients taking theophylline should be advised to seek medical help if they develop signs of theophylline toxicity such as palpitations or nausea
- Patients taking methadone should be advised to alert for signs of opioid toxicity
- Information that varenicline may have minor or moderate influence on their ability to drive and use machines. Varenicline may cause dizziness and somnolence and therefore may influence the ability to drive and use machines. Patients are advised not to drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether this medicinal product affects their ability to perform these activities
- Advice that discontinuation of varenicline is associated with an increase in irritability, urge to smoke, depression and/or insomnia in up to 3% of patients and this may need to be managed at the end of treatment.

Patients should also receive the following general advice on:

- Withdrawal symptoms
- Possible changes in the body on stopping smoking e.g., weight gain
- Other services that may help them stop smoking

Patients should also be informed about:

- Arrangements for accessing on going treatment during the 12/24 weeks (including carbon monoxide (CO) levels checks).
- Information obtained in this consultation will be shared with their GP and Rochdale’s stop smoking services and they must consent to this in order to access the service.

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### 6. References used to develop this PGD

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2. NICE Quality standard QS43, [Smoking: supporting people to stop](#), August 2013.
3. NICE Quality standard QS92, [Smoking: harm reduction](#). July 2015.
4. NICE Guideline NG92, [Stop smoking interventions and services](#), March 2018
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6. NICE Medicines practice guideline MPG2, [Patient group directions](#), March 2017
7. Manufacturer's Summary of Product Characteristics (SmPC) [CHAMPIX 0.5 mg film-coated tablets; CHAMPIX 1 mg film-coated tablets](#), Pfizer Limited. Date of last revision of the text 11/2020, accessed via eMC on the 17<sup>th</sup> September 2021.
8. NICE Clinical Knowledge Summaries CKS, [Smoking Cessation](#), last revised in November 2020
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12. UKMi, Medicines Q&As, [Which medicines need dose adjustment when a patient stops smoking?](#), August 2012
13. UKMi, Medicines Q&As, [What are the clinically significant drug interactions with tobacco smoking?](#), July 2020
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19. Specialist Pharmacy Service, [PGD template](#), March 2021
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21. U.S. Food and Drug Administration, Drug Safety Communications, [FDA updates label for stop smoking drug Chantix \(varenicline\) to include potential alcohol interaction, rare risk of seizures, and studies of side effects on mood, behaviour, or thinking](#), 3/9/2015
22. Campagna A. et al., [Smoking and diabetes: dangerous liaisons and confusing relationships](#), October 2019

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**7. Pharmacist authorisation sheet**

Varenicline PGD v4.0      Valid from 11/01/2022      Expiry: 10/01/2024

**Pharmacist**

By signing this PGD you are indicating that you agree to its contents and that you will work within it. PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

<b>I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.</b>			
Name	Designation	Signature	Date

**Authorising manager**

<b>I confirm that the pharmacists named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of <b>INSERT NAME OF ORGANISATION</b> for the above named pharmacists who have signed the PGD to work under it.</b>			
Name	Designation	Signature	Date

**Note to authorising manager**

Score through unused rows in the list of pharmacists to prevent additions post managerial authorisation.

A copy of this PGD with completed pharmacist authorisation sheet should be retained and available at the pharmacy premises as a record of those pharmacists authorised to work under this PGD.

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## Appendix 1

### Client Assessment Form Guidance for Stop Smoking Advisors How to complete and why?

**Reference:** [CHAMPIX 0.5 mg film-coated tablets](#); [CHAMPIX 1 mg film-coated tablets](#)

For clients who prefer varenicline for their smoking cessation therapy, the following form ('Client assessment form for varenicline') should be completed.

#### Social history

It is also important to consider a person's social history. Often a person will not realise that their level of alcohol consumption is excessive and they should be encouraged to be honest about their level of drinking. Those clients that drink excessively may benefit from referral to other services for support to reduce their alcohol drinking

#### Screening questions – Medical history

Clients that have depression, anxiety or other mental health disorders (including eating disorders) should be informed that stopping smoking may increase their risk of impulsive self-harm or suicide regardless of treatment option used. These clients are still eligible for treatment with varenicline under the Patient Group Direction (PGD), however, if receiving treatment (pharmacological or counselling/listening services) for their mental health disorder they should be advised to let the person responsible for their care know that they are stopping smoking.

Patients with schizophrenia or schizoaffective disorder should be advised that the evidence for the use of varenicline is not sufficiently clear to allow its use in this patient group.

Patients with renal impairment (kidney problems) or unstable cardiovascular disease (e.g., angina or awaiting treatment for a heart condition), they should be referred to their GP for further assessment (where available) or they can be offered treatment with NRT.

Patients that have been diagnosed with a seizure (fits) disorder should be referred to their GP for further assessment (where available) or they can be offered treatment with NRT.

If the client is taking cimetidine, they should be referred to their GP for further assessment (where available) or they can be offered treatment with NRT.

#### General

Although the client can decide which option they prefer, it should be stressed that the pharmacist may still not be able to supply varenicline under the PGD due to their medical condition(s) or medication.

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**Appendix 2**

**Client Assessment Form**

**Note: During COVID19 pandemic this information can be collected on paper using this form, or electronically using the web-based platform provided by the commissioner for the purposes of recording data associated with service delivery.**

**Client Assessment Form for Varenicline**

As you have chosen to consider varenicline as your medication to help you stop smoking, please complete the questions below. As it has already been discussed with you, this treatment has side effects. These medicines are not appropriate for everyone if you have certain medical conditions or other medicines that may interfere with these treatments. If you do not answer a question or want to speak to a smoking advisor/pharmacist confidentially, please highlight this to them.

If you are commenced on varenicline a letter will be sent to your GP to inform them, you must consent to this in order to receive treatment via your pharmacist. The GP will be asked to contact us if they have any concerns about you receiving this treatment due to additional information they may hold.

**Screening questions**

Q1.	Are you under the age of 18 years?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Q2.	Are you pregnant or breastfeeding?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Q3.	Are you currently using other smoking cessation therapies?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Q4.	Are you allergic or intolerant to varenicline or any of the excipients?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Q5.	Have you ever been diagnosed with a seizure (fits) disorder?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Q6.	Has your doctor informed you that you have reduced kidney function, also called renal impairment?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Q7.	Do you have unstable cardiovascular disease e.g., angina, awaiting treatment for a heart condition?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Q8.	Do you have schizophrenia or schizoaffective disorder?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Q9.	Do you take cimetidine?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

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**Medication history**

Please provide a list of your current medication including herbal remedies and purchased medicines.....