

PATIENT GROUP DIRECTION FOR THE SUPPLY OF

Varenicline 0.5mg and 1mg Film Coated Tablets

By pharmacists for smoking cessation in
community pharmacy

Version 3.2

Valid from: 11/01/2020

Expires on: 10/01/2022

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.

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DOCUMENT CONTROL – PGD Ready for authorisation

Document Location

Copies of this PGD can be obtained from:

Name:	Rochdale Metropolitan Borough Council
Address:	No. 1 Riverside, Smith Street, Rochdale OL16 1XU
Telephone:	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	
19/09/2019 S Woods	1. Characteristics of Staff Under 'Additional requirements' added link to DoC on CPPE website. 3. Details of medicine Under 'Identification & management of adverse reactions' updated Very common and Common adverse reactions in line with SPC.	2.1	
19/11/2019 S Woods	6. References used to develop this PGD All references checked and updated.	2.2	
26/11/2019 S Woods	Correction of valid from and to dates. 1. Characteristics of Staff Under 'Additional requirements' brought in line with other PGDs – added the bullet points: <ul style="list-style-type: none"> ▪ Has undertaken training in the use of PGDs ▪ Has undertaken 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. ▪ Is competent in the assessment of the individuals using Fraser guidelines 	2.3	
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	
	PGD section		Changes made
	Indication (Clinical condition or situation to which this PGD		Addition of the second bullet point: <ul style="list-style-type: none"> • Receiving specialist advice and support from a pharmacy

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	applies)	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	
18/11/2020 K Osowska	Criteria for inclusion	Replacing bullet point <ul style="list-style-type: none"> A full medical history has been taken and documented with bullet point <ul style="list-style-type: none"> 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' 	3.1
	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	
	Presentation	'Titration pack' amended to 'treatment initiation pack'	
	Quantity to be administered and/or supplied	Quantity was amended from 3 supplies to 4 supplies as following: 1 st supply -2 weeks 2 nd supply – 4 weeks 3 rd supply- 4 weeks 4 th supply – 2 weeks Addition of the note reflecting on the provision of the service during COVID 19 pandemic: '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	

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		timely fashion. Supplies made utilising this temporary adjustment should be recorded as such. ‘	
18/11/2020 K Osowska	Appendix 2	<ul style="list-style-type: none"> Addition of the note reflecting on recording the consultation during COVID19 pandemic Removal of the requirement of obtaining written consent from the patient. <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> <ul style="list-style-type: none"> 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. <p>Changed to:</p> <ul style="list-style-type: none"> 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. 	
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)	

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		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.	

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Approvals

This PGD must be approved by the following before distribution:

NAME	TITLE	DATE OF ISSUE	VERSION
Dr Richard Darling	GP, Prescribing Lead Heywood, Middleton & Rochdale CCG	21/01/2021	3.2
Andrew Martin	Strategic Medicines Optimisation Pharmacist, GM Joint Commissioning Team	18/12/2020	3.2
Andrea Fallon	Director of Public Health, Rochdale Metropolitan Borough Council	03/02/2021	3.2
Luvjit Kandula	Director of Pharmacy Transformation GM LPC	28/01/2021	3.2

Distribution

This PGD has been distributed to during its development:

NAME	TITLE	DATE OF ISSUE	VERSION
Dr A York	Clinical Lead Heywood, Middleton & Rochdale CCG	20/09/2019	2.1
		27/11/2019	3.0
Dr Richard Darling	GP, Prescribing Lead Heywood, Middleton & Rochdale CCG	18/11/2020	3.1
		21/12/2020	3.2
Gary Pickering	GM LPC Representative	20/09/2019	2.1
		27/11/2019	3.0
Luvjit Kandula	Director of Pharmacy Transformation GM LPC	18/11/2020	3.1
		21/12/2020	3.2
Dr Keith Pearson	Head of Medicines Optimisation, HMR CCG	20/09/2019	2.1
		27/11/2019	3.0
		18/11/2020	3.1
Andrew Martin	Strategic Medicines Optimisation Pharmacist, GM Joint Commissioning Team	20/11/2019	2.2
		27/11/2019	3.0
		18/11/2020	3.1
		21/12/2020	3.2

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PGD Development

Originally developed / Reviewed by:	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 A York	Clinical Lead Heywood, Middleton & Rochdale CCG
	Dr Richard Darling	GP, Prescribing Lead Heywood, Middleton & Rochdale CCG
	Luvjit Kandula	Director of Pharmacy Transformation GM LPC
	Dr Keith Pearson	Head of Medicines Optimisation, Heywood, Middleton & Rochdale CCG

Date applicable:	11/01/2020
Review date:	01/08/2021
Expiry date:	10/01/2022

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		18/12/20
Doctor (GP, Prescribing Lead Heywood, Middleton & Rochdale CCG)	Dr Richard Darling		21/1/21
Pharmacist Representative (Director of Pharmacy Transformation GM LPC)	Luvjit Kandula		28/1/21

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Pharmacist Reviewer (Advanced Medicines Optimisation Pharmacist GMJCT)	Karina Osowska		18.12.20
Authorised Signatory for Rochdale Metropolitan Borough Council (Director of Public Health)	Andrea Fallon		03/02/21

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1. Characteristics of Staff

Qualifications required	<ul style="list-style-type: none"> ▪ Pharmacist with a current General Pharmaceutical Council registration ▪ Work in a Community Pharmacy within Rochdale Metropolitan Borough Council area.
Additional requirements	<ul style="list-style-type: none"> ▪ Has undertaken training in the use of PGDs ▪ Has undertaken 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. ▪ Has 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"> ◆ <i>Stop smoking advisor</i> ◆ <i>Pharmacist supply of Prescription Only Medicines via PGD document.</i> Available here: https://www.cppe.ac.uk/services/declaration-of-competence#navTop. ▪ Is competent in the assessment of the individuals using Fraser guidelines
Continued training requirements	<ul style="list-style-type: none"> ▪ The pharmacist should be aware of any change to the recommendations for the medicine listed. ▪ Must be able to show regular update in the field of smoking cessation services and their delivery. ▪ Must assess and maintain their own competence 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"> ◆ <i>Stop smoking advisor</i> ◆ <i>Pharmacist supply of Prescription Only Medicines via PGD document.</i> ▪ It is the responsibility of the pharmacist to keep up-to-date with continuing professional development. ▪ 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.
Suggested supporting learning	<p>It is essential that pharmacists complete and satisfy the competencies detailed in the CPPE <i>Declaration of Competence for pharmacy services – Smoking Cessation Intervention Service</i>:</p> <ul style="list-style-type: none"> ◆ <i>Stop smoking advisor</i> ◆ <i>Pharmacist supply of Prescription Only Medicines via PGD document.</i>

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.

<p>Indication (Clinical condition or situation to which this PGD applies)</p>	<p>Provision of varenicline to tobacco users who are:</p> <ul style="list-style-type: none"> • 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 • 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
<p>Criteria for inclusion</p>	<ul style="list-style-type: none"> ▪ Tobacco users identified as sufficiently motivated to quit (willing to set a quit date between days 8 and 14 of starting treatment) and receive weekly face to face motivational support for the first four weeks at least ▪ Patients aged 18 years or over ▪ Consent has been obtained and recorded ▪ 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 ▪ There are no contraindications or cautions for treatment with varenicline. ▪ 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)
<p>Criteria for exclusion¹</p>	<ul style="list-style-type: none"> ▪ No valid consent to share information with their GP and Rochdale’s stop smoking services ▪ If referred by the Rochdale’s stop smoking team, no initial referral letter or confirmation letter of ongoing support ▪ Use with other smoking cessation therapies ▪ Tobacco users who are not sufficiently motivated to quit or use varenicline ▪ 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) ▪ Patients under the age of 18 years ▪ Pregnant or breastfeeding mothers ▪ Hypersensitive to varenicline or any of the excipients ▪ Known renal impairment ▪ Unstable cardiovascular disease (e.g. angina) ▪ All patients who have answered ‘Yes’ to any question on the client assessment form ▪ Patients with epilepsy or a history of seizures ▪ Patients with schizophrenia or schizoaffective disorder

¹ 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 another form of authorisation may be suitable.

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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.
- Cautions relevant to all smoking cessation attempts, not specific to using varenicline:
 - ♦ Theophylline is metabolised principally via CYP1A2. Smokers need higher doses of theophylline than non-smokers due to theophylline's shortened half-life and increased elimination. Some reports suggest smokers may need twice the dose of non-smokers. 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.

Cautions (including

- ♦ Warfarin is partly metabolised via CYP1A2. An interaction with

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<p>any relevant action to be taken)</p> <p>Continued from previous page.</p>	<p>smoking is not clinically relevant in most patients. The dose of warfarin is adjusted according to a patient's INR (International Normalised Ratio). Advise patients to tell the clinician managing their anticoagulant control that they are stopping smoking.</p> <ul style="list-style-type: none"> ◆ 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. ◆ Methadone is metabolised via 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.
<p>Action if excluded</p>	<ul style="list-style-type: none"> ▪ Consider other forms of smoking cessation therapy i.e. Nicotine Replacement Therapy (NRT). ▪ Refer to Rochdale's stop smoking service for further support or to their GP for further assessment where available
<p>Action if patient or carer declines treatment</p>	<ul style="list-style-type: none"> ▪ Inform patient re risks of not receiving treatment compared to the benefits. ▪ Consider other forms of smoking cessation therapy i.e. Nicotine Replacement Therapy (NRT). ▪ Refer to Rochdale's stop smoking service for further support or to their GP for further assessment where available

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3. Details of medicine

<p>Name, strength & formulation of drug</p>	<p>0.5 mg film-coated tablets and 1 mg film-coated tablets containing 0.5mg or 1mg of varenicline (as tartrate).</p> <p>Current Brand available is Champix®:</p> <p>0.5 mg film-coated tablets: White, capsular-shaped, biconvex tablets debossed with “Pfizer” on one side and “CHX 0.5” on the other side.</p> <p>1 mg film-coated tablets: Light blue, capsular-shaped, biconvex tablets debossed with “Pfizer” on one side and “CHX 1.0” on the other side.</p>
<p>Presentation</p>	<ul style="list-style-type: none"> ▪ 500 micrograms 56-tab pack ▪ 1 mg 28-tab pack & 56-tab pack ▪ Treatment initiation pack of 11 x 500-microgram tabs with 14 x 1-mg tabs
<p>Legal category</p>	<p>POM</p>
<p>Black Triangle ▼</p>	<p>No</p>
<p>Unlicensed / off label use</p>	<p>Use of varenicline for <12 weeks is an off label use</p>
<p>Route / method</p>	<ul style="list-style-type: none"> ▪ Oral administration. ▪ Swallow tablets whole with water. ▪ Take with or without food.
<p>Dose and frequency</p>	<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"> ▪ Days 1-3: <ul style="list-style-type: none"> ◆ 0.5mg once daily ▪ Days 4-7: <ul style="list-style-type: none"> ◆ 0.5mg twice daily ▪ Day 8 – end of treatment (12 weeks): <ul style="list-style-type: none"> ◆ 1mg twice daily <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> <p>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.</p>

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Quantity to be administered and/or supplied

- 1st supply - 2 weeks (Treatment initiation pack – see 'Presentation')
- 2nd supply - 4 weeks
- 3rd supply - 4 weeks
- 4th supply - 2 weeks

- 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.
- Labelling requirements: Products must be labelled in accordance with the requirement of the Medicines Act.

Note reflecting on provision of the service during COVID 19 pandemic:

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. ²

Maximum or minimum treatment periods

Maximum of 12 weeks treatment.

Drug interactions⁴

- If the patient is taking any concomitant medication or treatment it is the practitioner's responsibility to ensure that treatment with the drug detailed in this PGD is appropriate. (For drug interaction see Appendix 1 of BNF (<https://www.medicinescomplete.com/mc/>) or the SPC (<http://www.medicines.org.uk/emc/>) or contact the Medicine Information Service at Liverpool – telephone number inside front cover of BNF
- In the case of any doubt, further advice must be sought from an appropriate health professional and recorded as having been sought before the drug is given.
- If the requirements of this Patient Group Direction cannot be complied with the patient must be referred to a suitable independent prescriber.

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

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Identification & management of adverse reactions²

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.

▪ **Very common (> 1/10)**

Nasopharyngitis, headache, abnormal dreams, insomnia, nausea.

▪ **Common (>1/100, <1/10)**

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.

▪ See SPC (<http://www.medicines.org.uk/emc/>) or current BNF (<http://www.bnf.org/bnf/index.htm>) online for full details.

▪ If appropriate report the adverse reaction under the Yellow Card scheme (forms can be found at the back of the BNF or completed online at <http://yellowcard.mhra.gov.uk>)

4. Records

Records

▪ The following should be recorded as a minimum:

- ♦ Name of product
- ♦ Date supplied.
- ♦ Batch Number.
- ♦ Expiry date.
- ♦ Name of pharmacist who supplied the medicine.
- ♦ Advice given.
- ♦ Advice given if excluded or declines treatment.
- ♦ Prescription charges collected
- ♦ Consent to share information

▪ The patient's GP should be informed that the patient has been supplied with varenicline within 2 working days from the date of issue.

▪ Data must be stored in accordance with Caldicott guidance and the Data Protection Act.

▪ All records should be clear, legible and contemporaneous.

▪ A computerised or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes.

Records Management Code of Practice for Health and Social Care 2016 recommends the following storage periods for health records:

▪ 8 years (in adults) or until 25th birthday in a child (age 26 if entry made when young person was 17), or 8 years after death. -

<https://digital.nhs.uk/article/1202/Records-Management-Code-of-Practice-for-Health-and-Social-Care-2016>)

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5. Patient Information

<p>Written information to be given to the patient or carer</p>	<p>The patient should be given the following written information if appropriate:</p> <ul style="list-style-type: none"> ▪ The product specific patient information sheet supplied with the medicine. ▪ Any other suitable information with regard to their treatment and services available.
<p>Advice to be given to the patient or carer</p>	<p>Patients should be given the following information verbally if appropriate:</p> <ul style="list-style-type: none"> ▪ Information on using the initiation pack at the first supply. ▪ Information on possible side effects and their management. ▪ Made aware of the possible emergence of depressive symptomatology when attempting to stop smoking. ▪ Made aware of the need to discontinue treatment at the first sign of a rash or skin reaction and to seek medical advice immediately. ▪ Made aware of the need to discontinue treatment if any of the following clinical signs occur: <ul style="list-style-type: none"> ♦ swelling of the face (tongue, lips and gums) ♦ neck ♦ extremities and/or ♦ difficulty breathing and to seek medical advice immediately. ▪ Advised to seek medical advice should other symptoms develop after treatment has started ▪ Advised 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 ▪ Diabetic patients should be advised to be extra vigilant for symptoms of hypoglycaemia and to monitor their blood glucose more frequently ▪ If taking warfarin they should be advised to inform their anticoagulant clinic or whoever monitors their INR that they are stopping smoking ▪ Advised 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. <p>Patients should also receive the following general advice on:</p> <ul style="list-style-type: none"> ▪ Withdrawal symptoms ▪ Possible changes in the body on stopping smoking e.g. weight gain ▪ Other services that may help them stop smoking <p>Patients should also be informed about:</p> <ul style="list-style-type: none"> ▪ Arrangements for accessing on going treatment during the 12/24 weeks ▪ 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

1. National Institute for Health and Care (NICE).
 - Smoking: harm-reduction. NICE Guidance PH45, July 2013. Available at <http://www.nice.org.uk/guidance/PH45> accessed 19th Sept 2019.
 - Smoking: supporting people to stop. NICE Quality Standard QS43, August 2013. Available at <https://www.nice.org.uk/guidance/qs43> accessed 19th Sept 2019.
 - Smoking: Harm reduction. NICE Quality Standard QS92, July 2015. Available at <https://www.nice.org.uk/guidance/qs92/> accessed 19th Sept 2019.
 - Stop smoking interventions and services. NICE Guidance NG92, March 2018. Available at <https://www.nice.org.uk/guidance/ng92> accessed 19th Sept 2019.
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2. Manufacturer’s Summary of Product Characteristics (SPC)
 - CHAMPIX 0.5 mg film-coated tablets; CHAMPIX 1 mg film-coated tablets, Pfizer Limited. Date of last revision of the text 23/07/2019. Available at <https://www.medicines.org.uk/emc/search?q=%22Champix%22> accessed 19th Sept 2019.
3. CKS (Clinical Knowledge Summaries)
 - Smoking Cessation (last revised in March 2018). Available at <https://cks.nice.org.uk/smoking-cessation> accessed 20th Sept 2019.
4. NICE Guidance
 - Patient Group Directions, Medicines practice guideline [MPG2] (published August 2013, last updated March 2017). Available at <https://www.nice.org.uk/guidance/mpg2> accessed 19th Sept 2019.
5. General Pharmaceutical Council.
 - Standards for pharmacy professionals, May 2017. <https://www.pharmacyregulation.org/standards-for-pharmacy-professionals> Accessed 19th Sept 2019.
 - Guidance to support the standards for pharmacy professionals. <https://www.pharmacyregulation.org/guidance/guidance-support-standards-pharmacy-professionals>. Accessed 19th Sept 2019.
6. NHS Digital
 - Records Management Code of Practice for Health and Social Care 2016. <https://digital.nhs.uk/article/1202/Records-Management-Code-of-Practice-for-Health-and-Social-Care-2016>. Accessed 19th Sept 2019.
7. Royal College of Psychiatrists, [The prescribing of varenicline and](#)

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[vaping \(electronic cigarettes\) to patients with severe mental illness](#),
PS05/18, December 2018

8. 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

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The Patient Group Direction is to be read, agreed to and signed by the healthcare professional and their employer. The healthcare professional retains a copy of the PGD. The employer retains a record of all PGDs held by healthcare professionals employed or contracted by them.

Individual Authorisation

By signing this PGD you are agreeing that:

- You have read and understood the content;
- To the best of your knowledge, the content of the PGD is correct and supports best practice;
- You will act within the parameters of the PGD;
- You take responsibility for maintaining your competence and ongoing training requirements to continue to use the PGD safely

Named Healthcare Professional: _____

Designation: _____

The above named healthcare professional is authorised to work within the confines of this Patient Group Direction

Name of Employer: _____
/ Contractor

Address of Employer: _____
/ Contractor

Signature of Employer: _____
/ Contractor

I, the undersigned, have read and understood this PGD and agree to work within its confines

Signature of Named

Healthcare Professional: _____

Date: _____

One copy to be retained by the named healthcare professional

One copy to be retained by the employer / contractor

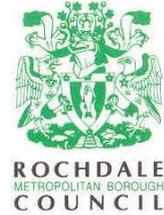
The healthcare professional's details must be recorded on a register of PGDs held by their employer/contractor.

Varenicline 0.5mg and 1mg Film Coated Tablets

P.O.M.
[Prescription Only Medicine]

Appendix 1

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



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

For clients who have a preference for varenicline (Champix®) 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 (Champix®) under the PGD due to their medical condition(s) or medication.

Varenicline 0.5mg and 1mg Film Coated Tablets

P.O.M.
[Prescription Only Medicine]

Reference: Summary of Product Characteristics for Champix® (10th June 2017)

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 (Champix®) 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 (Champix®) 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.	Have you used varenicline or bupropion within the last 3 months?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Q5.	Are you hypertensive to varenicline or any of the excipients?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Q6.	Have you ever been diagnosed with a seizure (fits) disorder?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Q7.	Has your doctor informed you that you have reduced kidney function, also called renal impairment?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Q8.	Do you have unstable cardiovascular disease e.g. angina, awaiting treatment for a heart condition?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Varenicline 0.5mg and 1mg Film Coated Tablets	P.O.M. [Prescription Only Medicine]
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Q9.	Do you have schizophrenia or schizoaffective disorder?	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.