South Yorkshire and Bassetlaw QUIT
Supported by Yorkshire Cancer Research
Treating Tobacco Addiction

CCG Logo

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

# PATIENT GROUP DIRECTION (PGD)

## Supply of

# Varenicline tablets

## in

# South Yorkshire and Bassetlaw (SYB) community pharmacies commissioned to provide treatment to patients being supported in the community on QUIT Programme pathways

Version Number 1.0

| Change History | |
|---|---|
| **Version and Date** | **Change details** |
| Version 1.0 February 2021 | New template |

Each organisation using this PGD must ensure that it is formally signed by a senior pharmacist, a senior doctor and any other professional group representatives involved in its review and that it is reviewed in line with the organisations' PGD governance system. The organisation's governance lead must sign to authorise the PGD on behalf of the authorising organisation to ensure that this document meets legal requirements for a PGD.

This Patient Group Direction (PGD) must only be used by registered professionals who have been named and authorised by their organisation to practise under it (See Appendix A). The most recent and in date final signed version of the PGD must be used.

## PGD DEVELOPMENT GROUP

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| Date PGD template comes into effect: | 1st May 2021 |
| Review date | November 2023 |
| Expiry date: | 30th April 2024 |

This PGD template has been developed and agreed by the listed members of the QUIT PGD development group.

**This section MUST REMAIN when a PGD is adopted by an organisation.**

| Name | Designation |
|---|---|
| Emily Parsons | Medicines Governance Pharmacist<br>NHS Sheffield CCG |
| Steve Freedman | Community Services Lead Pharmacist<br>Sheffield Clinical Commissioning Group |
| Dr Lisa Wilkins | Consultant in Public Health Medicine<br>South Yorkshire and Bassetlaw Integrated Care System |
| Maggie Milne | Service Manager<br>Yorkshire Smokefree Sheffield<br>South West Yorkshire Partnership NHS Foundation Trust |
| Sarah Hudson | Lead Pharmacist Barnsley and Medicines Safety Officer<br>South West Yorkshire Partnership NHS Foundation Trust |
| Thomas Bisset | Community Pharmacist, Barnsley Local Pharmaceutical Committee |
| Claire Thomas | Chief Officer, Sheffield Local Pharmaceutical Committee |

**To enable consistent service delivery across South Yorkshire and Bassetlaw, each Clinical Commissioning Group in South Yorkshire and Bassetlaw will approve and adopt this standard patient group direction for varenicline supply as part of the QUIT Programme.**

**Sheffield Clinical Commissioning Group undertakes to regularly review and update the patient group direction and share revised versions with the other South Yorkshire and Bassetlaw Clinical Commissioning Groups. SYB CCGs should contact Sheffield CCG if at any point they wish the PGD to be amended.**

**The PGD template is not legally valid until it has had the relevant organisational approval - see below.**

## ORGANISATIONAL AUTHORISATIONS AND OTHER LEGAL REQUIREMENTS

Authorisation is limited to those registered healthcare professionals listed in Appendix A.

Any practitioner intending to work under the PGD must be individually authorised by their / the designated manager, under the current version of this PGD before working according to it (see Appendix A). Each registered healthcare professional is professionally accountable for ensuring they have undergone appropriate smoking cessation training and are approved as competent to supply varenicline tablets only in accordance with the following patient group direction.

The registered healthcare professional must act within their code of professional conduct at all times.

The PGD template has been reviewed and authorised by:

The PGD is not legally valid until it has had the relevant organisational authorisations.
To ensure compliance with the law, organisations must add local authorisation details i.e. clinical authorisations and the person signing on behalf of the authorising organisation. You may either complete details below or delete and use a format agreed according to local PGD policy which complies with PGD legislation and NICE MPG2 PGD 2017.

| Name | Job title and organisation | Signature | Date |
|---|---|---|---|
| **Senior doctor** | | | |
| **Senior pharmacist** | | | |
| **Senior representative of professional group using the PGD** | | | |
| **Person signing on behalf of authorising body** | | | |

## 1. Characteristics of staff

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| **Qualifications and professional registration** | Pharmacist registered with the General Pharmaceutical Council (GPhC), with a current contract of employment or locum agreement with a community pharmacy commissioned to provide treatment by PGD to patients being supported in the community on SYB QUIT Programme pathways. |
| **Initial training** | The pharmacist authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of patients ensuring safe provision of the medicines listed in this PGD.<br><br>Suggested requirement for training would be successful completion of a relevant smoking cessation module / course accredited or endorsed by the CPPE or NCSCT.<br><br>The pharmacist must have read and understand the most up-to-date QUIT Tobacco Addiction Treatment E-Voucher Scheme Service Specification.<br><br>The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults or level 2 safeguarding or the equivalent. |
| **Competency assessment** | Individuals operating under this PGD must complete a self-declaration of competence for the supply of varenicline by PGD.<br><br>Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions. |
| **Ongoing training and competency** | Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required.<br><br>Organisation PGD or medication training as required by employing organisation or commissioning service. |
| The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies. | |

## 2. Clinical condition or situation to which this PGD applies

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| **Clinical condition or situation to which this PGD applies** | Patients referred to a community pharmacy by a SYB NHS Trust Tobacco Treatment Advisor (TobTA)* via PharmOutcomes as part of the QUIT E- Voucher Scheme Pathway.<br><br>*Please note that throughout this document the use of the term Tobacco Treatment Advisor (TobTA) should be taken to also include other appropriately trained members of the Trust's QUIT specialist team including the Healthy Hospital Programme Manager, Healthy Hospital Project Manager and Health Improvement Managers. |
| **Criteria for inclusion** | • Individuals over 18 years of age<br>• Consent gained<br>• Individuals receiving support from an SYB Trust TobTA as part of the QUIT Tobacco Addiction Treatment E-Voucher Scheme service<br>• Valid e-voucher on PharmOutcomes<br>• Individuals registered with a GP in the following NHS CCGs:<br>  ○ Barnsley<br>  ○ Bassetlaw<br>  ○ Doncaster<br>  ○ Rotherham<br>  ○ Sheffield |
| **Criteria for exclusion** | • Individuals under 18 years of age<br>• Consent not gained<br>• Sensitivity to varenicline tablets or any of its excipients<br>• Pregnancy / suspect pregnancy<br>• Breastfeeding<br>• Individuals already receiving varenicline prescribed by a GP<br>• Individuals currently receiving treatment from a local community stop smoking / integrated wellbeing service*<br>• End stage renal disease<br>• Epilepsy or history of fits or seizures or conditions where the seizure threshold may be lowered<br>• Individuals who have experienced serious or worrying side effects from a previous course of varenicline<br>• Individuals with a history of serious psychiatric illness such as schizophrenia, bipolar disorder or major depressive illness.<br><br>*Note - Individuals who were under the care of the local community stop smoking service (SSS) prior to hospital admission will have this support paused temporarily while an inpatient and until after the first follow up call post discharge by the Trust TobTA. Thus, it is acceptable for community pharmacists to supply medication for these individuals as requested by Trust TobTAs prior to the community SSSs picking up the care again. |
| **Cautions including any relevant action to be taken** | **Renal impairment**<br>• *Mild (CrCl > 50 ml/min to ≤ 80 )* – No dose adjustment required<br><br>• *Moderate (≥ 30 to ≤ 50 ml/min)* – No dose adjustment required, except if the patient develops intolerable adverse reactions. See dose section<br><br>• *Severe (CrCl < 30 ml/min)* – dose adjustments required. See dose |

section.

**Neuropsychiatric Symptoms**

- The EAGLES study (April 2016) has provided evidence that the use of varenicline in clients with or without a history of psychiatric disorder was not associated with a significantly increased risk of serious neuropsychiatric adverse events compared with placebo.

**Patients with History of Psychiatric Disorders**

- Smoking cessation, with or without pharmacotherapy, has been associated with the exacerbation of underlying psychiatric illness (e.g. depression). Care should be taken with clients with a history of psychiatric illness. If this is a consideration, community pharmacists should liaise with the clients GP or mental health team prior to smoking cessation.

**Effect of Smoking Cessation:**

- Cigarette smoke stimulates a liver enzyme responsible for metabolising some medicines in the body, such as theophylline, warfarin, insulin, flecainide, olanzapine and clozapine, meaning that the metabolism of these medications increases. Clients should be warned that physiological changes resulting from smoking cessation, with or without treatment with varenicline, may alter the pharmacokinetics or pharmacodynamics of some medicinal products for which dose adjustment may be necessary.
- Any dose adjustments need to be individually tailored. See '<u>What are the clinically significant drug interactions with tobacco smoking?</u>' guidance from SPS for more detailed advice on drugs affected and how to manage.
- If a client is taking one of the affected medicines and is still smoking/using NRT at the time of review, ensure their GP or prescribing specialists are notified of their quit attempt/use of varenicline. PharmOutcomes will send an automatic notification to GPs of all patients commencing varenicline (irrespective of what drugs they are on). The notification will include a list of the drugs noted in the SPS guidance as having a high or moderate clinical significance if the patient stops smoking, with a prompt for the GP to review the patient's medication.
    - When the client stops smoking, metabolism of **theophylline** is reduced which could cause plasma theophylline levels to rise, possibly to toxic levels if the dose of theophylline is not adjusted. The GP/prescribing specialist need to be informed of the intention to stop smoking prior to quitting. Signs of theophylline toxicity are vomiting, dilated pupils, sinus tachycardia and hyperglycaemia
    - Clients on **warfarin**, should advise the clinic of their intention to quit smoking using varenicline when they next attend for a blood test
    - Clients on **insulin** may be supplied with varenicline. However, they should be advised to monitor their blood glucose levels closely
    - Clients taking **antipsychotics (and other medications effected by smoking cessation)** should advise their GP and / or Mental Health Team of their intention to stop smoking prior to quitting

**Please note**: The above list of medications is not exhaustive and

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| | further clarification using relevant reference sources, cross referencing the client's current medication profile, should be made by the pharmacist supplying any smoking cessation product. |
| **Action to be taken if the patient is excluded or declines treatment** | • Notify the referring Tobacco Treatment Advisor Service via PharmOutcomes, on the same day as the consultation, with information regarding the reason for exclusion / decline.<br>• Advise patient that the TobTA will contact them and review their treatment plan.<br>• Record reasons for exclusion / decline in patient notes |

## 3. Description of treatment

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| **Name, strength & formulation of drug** | Varenicline (e.g. Champix®) tablets, including:<br><br>Varenicline 0.5 mg film-coated tablets<br>Varenicline 1 mg film-coated tablets |
| **Legal category** | POM |
| **Route / method of administration** | Oral |
| **Dose and frequency of administration** | The recommended dose is 1 mg varenicline twice daily following a 1-week titration as follows:<br><br>Days 1 – 3: 0.5 mg once daily<br>Days 4 – 7: 0.5 mg twice daily<br>Day 8 – End of treatment: 1 mg twice daily<br><br>**Special considerations:**<br><br>**Number of days into the quit attempt**<br>Individuals referred to the pharmacy may have been taking varenicline as a hospital inpatient. Pharmacists will need to establish how many days of treatment the patient has already taken to determine the appropriate dose to supply.<br>If the patient has had a break in treatment of more than 3 days a starter pack should be considered.<br><br>**Adverse effects**<br>Patients who cannot tolerate adverse reactions of varenicline may have the dose lowered temporarily or permanently to 0.5 mg twice daily<br><br>**Renal impairment**<br>• *Mild (CrCl > 50 ml/min to ≤ 80 )* – No dose adjustment required<br><br>• *Moderate (≥ 30 to ≤ 50 ml/min)* – No dose adjustment required, except if the patient develops adverse reactions that are not |

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| | tolerable – when dosing may be reduced to 1 mg once daily.<br><br>• *Severe (CrCl < 30 ml/min)* The recommended dose is 1 mg once daily. Dosing should begin at 0.5 mg once daily for the first 3 days then increased to 1 mg once daily.<br><br>**Lower dose at end of treatment (normally 12 weeks in total)**<br>In smoking cessation therapy, risk for relapse to smoking is elevated in the period immediately following the end of treatment. In patients with a high risk of relapse, dose tapering may be considered for the last couple of weeks of treatment, for example 0.5 mg twice daily<br><br>**Concurrent use of NRT and Varenicline**<br>As patients are unable to smoke in hospital, patients started on varenicline while in hospital may also be prescribed NRT, to run alongside the varenicline, for a time limited period. To reduce the risk of patients who have been discharged within two weeks of commencing varenicline starting to smoke again on discharge, community pharmacists may occasionally be asked to supply a patient with both NRT and varenicline. This should be for a time limited period, up to a maximum of two weeks. |
| **Duration of treatment** | 14 to 28 days – supply in manufacturer's original pack sizes. Duration supplied depends on dose (see below).<br><br>Patients should be assessed by the TobTA weekly for at least 4 weeks after the quit date, then fortnightly.<br><br>The total treatment course should not extend beyond 12 weeks. |
| **Quantity to be supplied** | Supply one pack only, in manufacturers original packs according to dose, as below:<br><br>Initiation pack – 1 x 25 tablets<br><br>1mg tablets – 1 x 28 tablets<br><br>0.5mg tablets – 1 x 56 tablets<br><br>Packs must be labelled with the following as a minimum – Patient name, date, medication name, dose and name of provider organisation. |
| **Storage** | Stock must be securely stored according to organisation medicines policy and in conditions in line with SPC, which is available from the electronic Medicines Compendium website |
| **Drug interactions** | No clinically significant drug interactions have been reported.<br><br>However, physiological changes resulting from smoking cessation, with or without treatment with varenicline, may alter the pharmacokinetics or pharmacodynamics of some medicinal products, for which dosage adjustment may be necessary (examples include theophylline, olanzapine, clozapine, flecainide, warfarin and insulin). See cautions section above for further advice.<br><br>A detailed list of drug interactions is available in the SPC, which is |

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| | available from the electronic Medicines Compendium website. |
| **Identification & management of adverse reactions** | A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website, and BNF.<br><br>The following side effects are common with varenicline (but may not reflect all reported adverse effects):<br><br>Frequencies are reported as:<br>Very common ( ≥1/10)<br>Common ( ≥1/100 to <1/10)<br><br>*Very common*<br>○ Nausea<br>○ Nasopharyngitis<br>○ Abnormal dreams<br>○ Insomnia<br>○ Headache<br>*Common*<br>○ Chest infection, inflammation of the sinuses<br>○ Increased weight, decreased appetite, increased appetite<br>○ Sleepiness, dizziness, changes in the way things taste<br>○ Shortness of breath, cough<br>○ Heartburn, vomiting, constipation, diarrhoea, feeling bloated, abdominal pain, toothache, indigestion, flatulence, dry mouth<br>○ Skin rash, itching<br>○ Joint ache, muscle ache, back pain<br>○ Chest pain, tiredness<br><br>Clients should also be asked at every consultation about nicotine withdrawal symptoms, including mood changes. **Smoking cessation with or without treatment** is associated with various symptoms. For example, dysphoria or depressed mood; insomnia, irritability, frustration or anger; anxiety; difficulty concentrating; restlessness; decreased heart rate; increased appetite or weight gain have been reported in clients attempting to stop smoking. Clinicians should be aware of the possible emergence of serious neuropsychiatric symptoms in clients attempting to quit smoking with or without treatment. **If serious neuropsychiatric symptoms occur clients should be advised to discontinue treatment and seek prompt medical advice.**<br><br>If the client develops suicidal thoughts or behaviour, they should be told to stop treatment and contact their GP immediately. The pharmacist should also inform the referring Trust Tobacco Treatment Advisor Service. |
| **Management of and reporting procedure for adverse reactions** | • Healthcare professionals and patients / carers are encouraged to report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme: https://yellowcard.mhra.gov.uk<br>• Record all adverse drug reactions (ADRs) in the patient's medical record.<br>• Report via organisation incident policy. |

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| **Written information and further advice to be given to individual** | Give the marketing authorisation holder's patient information leaflet (PIL) provided with the product.<br><br>Advice to patients should include specific product advice on dosage, method of administration and side effects.<br><br>• If it is the patients first supply of varenicline and the patient is still smoking:<br>  ○ Advise to set a quit date 7 to 14 days after initiation and provide advice regarding follow up and obtaining further supplies<br>• Monitor for side effects that may affect driving or using machinery<br>• General smoking cessation advice, particularly with regard to withdrawal symptoms. Please remember the change in ethos with the QUIT Programme considering smoking as a chronic addiction that should be treated like any other long-term condition, rather than a lifestyle choice.<br>• The major reasons for varenicline failure are:<br>  ○ Unrealistic expectations<br>  ○ Lack of preparation for the fact that the tablets may cause nausea<br>  ○ Insufficient or incorrect use<br>• It is important to make sure that the patient understands the following points:<br>  ○ Varenicline is an effective medication but effort and determination are also necessary<br>  ○ It works by acting on the parts of the brain which are affected by nicotine in cigarettes<br>  ○ It does not remove all temptation to smoke or all nicotine withdrawal symptoms, but it does make abstinence easier (‘it takes the edge off the discomfort’)<br>  ○ Varenicline is safe, but about a third of patients 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.<br>  ○ Instruct on correct use and daily dose. Use mock product packaging for the explanation.<br>  ○ Clients who are still smoking at time of review by the pharmacist should take varenicline for 7 to 14 days before stopping smoking. Patients started on varenicline as an inpatient at the referring Trust hospital may have been prescribed NRT alongside varenicline (instead of continuing to smoke). Explain to patients the NRT will only be needed for a total of 7 – 14 days.<br>  ○ If the patient experiences any extreme side effects they should seek medical advice immediately<br>• 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 |

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| **Patient advice / follow up treatment** | The individual/carer should be advised to seek medical advice in the event of an adverse reaction. The Trust TobTA should also be contacted.<br><br>Individuals should be advised that, in order to receive further supplies of varenicline, they need to be receiving ongoing support from either a community stop smoking service / integrated wellbeing service or the Trust TobTAs.<br><br>**Sources of information for patients:**<br><br>**General**<br>Quit smoking - https://www.nhs.uk/better-health/quit-smoking/<br>Quit for COVID - www.todayistheday.co.uk/<br><br>**Smokefree homes**<br>Family - https://smokefreesheffield.org/why-quit/family/<br>Passive smoking - www.nhs.uk/live-well/quit-smoking/passive-smoking-protect-your-family-and-friends/ |
| **Records** | Record the following, unless already recorded in patient record:<br><br>• that valid informed consent was given<br>• name of individual, address, date of birth and GP with whom the individual is registered (if relevant)<br>• name of registered pharmacist making the supply<br>• name of medication supplied<br>• date of supply<br>• dose, form and route of supply<br>• quantity supplied<br>• advice given, including advice given if excluded or declines treatment<br>• details of any adverse drug reactions and actions taken<br>• supplied via Patient Group Direction (PGD)<br><br>Records should be signed and dated (or a password controlled e-record).<br><br>All records should be clear, legible and contemporaneous.<br><br>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy. |

## 4. Key references

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| **Key references** | • Electronic Medicines Compendium http://www.medicines.org.uk/<br>• Electronic BNF https://www.medicinescomplete.com/#/content/bnf/_520176785<br>• NICE Medicines practice guideline “Patient Group Directions” https://www.nice.org.uk/guidance/mpg2<br>• QUIT Tobacco Addiction Treatment E-Voucher Scheme Service Specification. Available on PharmOutcomes and the SYB QUIT website: www.syb-quit.org.uk .<br>• SPS guideline “What are the clinically significant drug interactions |

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| | with tobacco smoking?" https://www.sps.nhs.uk/articles/what-are-the-clinically-significant-drug-interactions-with-tobacco-smoking/ |
| **Sources of additional information** | • NICE CKS for smoking cessation: https://cks.nice.org.uk/topics/smoking-cessation/<br>• National Centre for Smoking Cessation and Training: https://www.ncsct.co.uk/index.php<br>• Royal College of Psychiatrists - Position statement: 'The prescribing of varenicline and vaping (electronic cigarettes) to patients with severe mental illness': https://www.rcpsych.ac.uk/docs/default-source/improving-care/better-mh-policy/position-statements/ps05_18.pdf?sfvrsn=2bb7fdfe_4<br>• EAGLES study - Neuropsychiatric safety and efficacy of varenicline, bupropion, and nicotine patch in smokers with and without psychiatric disorders: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)30272-0/fulltext |

**Acknowledgement:**

SWYFT PGD for the supply of Varenicline tablets

## Appendix A – Registered health professional authorisation sheet

**Varenicline tablets PGD** **Version 1.0**
**Valid from: 1st May 2021** **Expiry: 30th April 2024**

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

### Registered health professional

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions 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.

| **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.** | | | |
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| **Name** | **Designation** | **Signature** | **Date** |
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### Authorising manager

| **I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of**<br>**INSERT NAME OF ORGANISATION** _____<br>**for the above named health care professionals who have signed the PGD to work under it.** | | | |
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| **Name** | **Designation** | **Signature** | **Date** |
| | | | |

### Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.