POLICY DOCUMENT

Patient Group Direction for the Supply of Varenicline by Community Pharmacists

Approved by:	**Leicestershire County Council Public Health Department**
On:	
Expiry Date:	**January 2020**
Directorate responsible for Review:	**Public Health Leicestershire County Councils)**
PGD Number:	**LLRPGD002**

Due Regard

The Council's commitment to equality means that this PGD has been screened in relation to paying due regard to the general duty of the Equality Act 2010 to eliminate unlawful discrimination, harassment, victimisation; advance equality of opportunity and foster good relations.

This document has been assessed to ensure that no one receives less favourable treatment on the protected characteristics of their age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation.

It is judged that it is not proportionate (equality relevant) in respect of this PGD as it specifically enables identified registered pharmacists to supply and administer medicines in accordance with national guidelines. Due regard has been given in respect of accessibility (larger print, Braille etc), including the provision of information or advice in an alternative language and consideration of patient carers and family members for support.

Patient Group Direction for the supply of Varenicline by designated community pharmacists across, Leicestershire and Rutland

Premises

From registered pharmacy premises which have been approved for this service by, Leicestershire County Council

Purpose of the PGD

For accredited pharmacists to supply Varenicline within its licensed indications as an option for smokers who have expressed a desire to quit smoking and who will be supported and monitored within a pharmacy accredited to issue Vaeranacline as part of a PGD. .

- Varenicline is a licensed Prescription Only Medicine as defined by the Medicines Act 1968 and Prescription Only Medicines (Human Use) Order 1997
- This PGD takes the place of a Prescription, as defined by The Human Medicines Regulations 2012
- This PGD will be reviewed every 12 months, or sooner, in light of any new guidance or information
- Clinical indications, Contraindications, and Cautions are as set out in the Summary of Product Characteristics
- Inclusion and Exclusion criteria are summarised within the PGD
- "Off Label" use is not supported by the PGD

Qualifications	• Registered Pharmacist currently on the practicing section of the pharmaceutical register held by the General Pharmaceutical Council that have completed the required training for accreditation and competency and , working within and for a pharmacy with an agreement with Leicestershire Council to provide varenicline under PGD. • Practitioners must hold a current and up to date Enhanced Disclosure and Barring Service check • It is the responsibility of the professional working under this PGD to verify that the client fulfils the stated criteria for supply of the treatment concerned • It is not appropriate to have a PGD in place that is infrequently used by health care professionals because of progressive unfamiliarity with its contents. Any healthcare professional that works to a PGD infrequently should consider whether to cease doing so • Must have completed the agreed Varenicline training programme. • This PGD will only apply whilst the pharmacist is employed or contracted/working at the time in an accredited Pharmacy within Leicestershire. • It is the responsibility of clinicians issuing Varenicline under the PGD to assess patients' suitability against the PGD Inclusion and Exclusion criteria and the SPC Indications/Contraindications. Patients falling outside of these criteria cannot receive Varenicline under the PGD. In this circumstance the patient needs to be referred back to the Stop Smoking Service for additional advice. **ALL HEALTHCARE PROFESSIONALS MUST BE AUTHORISED BY NAME UNDER THIS DIRECTION BEFORE USING IT.**
Method of Competency assessment	Before commencing the delivery of this service, all providers must have attended at least one face to face local training event. Pharmacists applying (or re-applying) to be on the Approved Provider List will have declared themselves competent using the Centre for Pharmacy Postgraduate Education (CPPE) Declaration of Competence for Community Pharmacy National Centre for Smoking Cessation and Training online training (accessed via CPPE) and will undertake to keep themselves up to date. Leicestershire County Council will approve pharmacies to provide the service in that locality and pharmacy providers, at the request of the commissioner, will be required to provide evidence to confirm that pharmacists have the necessary skills and competencies in accordance with the requirements of the contract.

Specialist competencies or qualifications	The pharmacist must be competent to assess a client's capacity to understand the nature and purpose of the treatment in order to give or refuse consent. Evidence of completion of approved CPPE training packages listed above and successful completion of their associated e-assessment. • CPPE's e-learning on Safeguarding vulnerable adults. • The CPPE e-assessments must be completed successfully in a timely way The practitioner must also attend a local workshop session, organised and delivered by the Leicestershire Stop Smoking Service.
Frequency of Competency review	Yearly
Accountability for competency assessment	Pharmacists will self-declare using the CPPE Declaration of Competence for Community Pharmacy Services
Accountability for staff involved in using the PGD	Pharmacists using the PGD are accountable to the Responsible Pharmacist and the Superintendent Pharmacist of the Pharmacy in which they are providing pharmaceutical services. The Responsible Pharmacist is responsible for the correct implementation of the PGD.
Continuing training & education	The practitioner should be aware of any change to the recommendations for Varenicline. It is the responsibility of the individual pharmacist to keep up-to-date with continued professional development and to work within the limitations of individual scope of practice. The practitioner must attend a local workshop session, organised and delivered by the Stop Smoking Service as a refresher every year.
Recording individual pharmacist authorisation	See **Appendix 1**

Referral Arrangements and Audit Trail

Additional Facilities and Referral Arrangements	The client must always be advised to continue to talk to/liaise with the Leicestershire Stop Smoking Service regardless of whether a supply is made. Where the circumstances are outside the PGD, or where there are medical concerns, or if the client wishes it, the client should be re-referred to the Stop Smoking Service using the Client Referral Form.
Records/audit trail	Records should be made on the Client Record Sheet (**Appendix 2**)

Ongoing Monitoring	
Method of auditing adherence to PGD	Adherence to the PGD will be monitored through the data submissions to Leicestershire County Council and mystery shopping/audit exercise
Frequency of audit	Annually
Accountability for audit and monitoring	Respective Consultant lead in Public Health at Leicestershire County Council

Supply of Varenicline for helping to stop smoking , by designated community pharmacists across , Leicestershire-Clinical Condition	
Indication	Varenicline as an option for clients wishing to quit smoking and who are being monitored by the Stop Smoking Service but who require varenicline to be dispensed in a community pharmacy setting
Inclusion criteria	• Clients over 18 years of age • Tobacco users identified as sufficiently motivated to quit • Tobacco users who are receiving support to stop smoking with Leicestershire Councils contracted Stop Smoking Service • A medical history is taken and documented to establish that there are no contraindications for treatment with varenicline and that any cautions for use are recorded (see Criteria for exclusion and Criteria for cautions). Refer to **Appendix 2** for *Assessment to Supply Varenicline*

Exclusion criteria	• Tobacco users not sufficiently motivated to quit or to use varenicline • Clients under 18 years of age • Sensitivity to varenicline or any of its excipients • Clients who have experienced serious or worrying side effects from a previous course of varenicline • Client already receiving varenicline prescribed by GP • Pregnancy/ breastfeeding • Renal impairment or end stage renal disease as decreased clearance by kidney increases side effects. • Epilepsy or history of fits or seizures • Substance misuse patients (taking methadone to be checked) • Clients with active or history of psychiatric illness should be referred to their GP
Actions if client excluded or if treatment declined by client	Pharmacists should direct the client back to their original Leicestershire contracted Stop Smoking Service Provider. Document action in client's medication record **Stop Smoking Service** referral proforma.

Cautions/Need for further advice (including consideration of concurrent medication)

- Smoking cessation, with or without pharmacotherapy, has been associated with the exacerbation of underlying psychiatric illness (e.g. depression). Clients with a history of psychiatric illness should be referred to their GP via the Stop Smoking Service:

    - Changes in behaviour or thinking, anxiety, psychosis, **mood swings,** aggressive behaviour, depression, suicidal ideation and behaviour and suicide attempts have been reported in patients attempting to quit smoking with Varenicline in the post-marketing experience.

    - A large randomised, double-blind, active and placebo-controlled study was conducted to compare the risk of serious neuropsychiatric events in patients with and without a history of psychiatric disorder treated for smoking cessation with Varenicline, bupropion, nicotine replacement therapy patch (NRT) or placebo. The primary safety endpoint was a composite of neuropsychiatric adverse events that have been reported in post-marketing experience. The use of Varenicline in patients with or without a history of psychiatric disorder was not associated with an increased risk of serious neuropsychiatric adverse

events in the composite primary endpoint compared with placebo (see section 5.1 **Pharmacodynamic properties** - *Study in Subjects with and without a History of Psychiatric Disorder*).

- 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

- Cigarette smoke stimulates a liver enzyme responsible for metabolising some medicines in the body, such as theophylline, warfarin and insulin, meaning that the metabolism of these medications increases. Patients 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 (examples include theophylline, warfarin and insulin). As smoking induces CYP1A2, smoking cessation may result in an increase of plasma levels of CYP1A2 substrates.

- If a client is a diabetic or is taking theophylline/aminophylline or warfarin, ensure their GP is notified of their quit attempt/use of varenicline using the letter provided with this PGD. (see **appendix 3**)
  - 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. Signs of theophylline toxicity are: - vomiting, dilated pupils, sinus tachycardia and hyperglycaemia
  - Patients on Warfarin, should advise the clinic of their intention to quit smoking using varenicline when they next attend for a blood test
  - Patients on insulin may be supplied with varenicline. However they should be advised to monitor their blood glucose levels closely

If in doubt about cautions, refer to or telephone the Stop Smoking Service
Please refer to the current BNF edition for further information.

Interactions

No clinical meaningful drug interactions have been reported.

Since metabolism of Varenicline▼ represents less than 10% of its clearance, active substances known to affect the Cytochrome P450 system are unlikely to alter the pharmacokinetics of Varenicline▼ and therefore a dose adjustment of Varenicline▼ would not be required.

However, levels of certain drugs taken by a patient once smoking has been stopped may be affected and thus, patients should be monitored for adverse effects. These drugs include:

- Caffeine
- Clozapine
- Dextropropoxyphene
- Flecainide
- Fluvoxamine
- Insulin
- Olanzapine
- Pentazocine

- Phenylbutazone e.g. Oxazepam
- Some beta blockers e.g. Propranolol
- Tacrine
- Theophylline
- Tricylic Antidepressants such as imipramine
- Warfarin

Please note: This list is not exhaustive and further clarification using relevant reference sources, cross referencing the patients current medication profile, should be made by the pharmacist supplying Varenicline▼

Drug Details

Name, form & strength of medicine	**Varenicline** (Champix®) 0.5mg and 1mg tablets
Route/Method	Oral administration
Licensing/Use of label	This is a Prescription Only Medicine Off Label use is not permitted
Dosage	**Days 1 – 3:** 0.5 mg (white tablets) once daily **Days 4 – 7:** 0.5 mg twice daily **Day 8 to the end of treatment (normally 12 weeks in total):** 1 mg (light blue tablets) twice daily Patients who cannot tolerate the adverse effects of varenicline can have the dose lowered temporarily or permanently to 0.5 mg twice daily. (See BNF 4.10.2). Smokers should set a date to stop smoking and treatment with Varenicline should commence 1 to 2 weeks before this date. **Titrate lower dose towards end of treatment (normally 12 weeks in total) if appropriate as directed by the Leicestershire Stop Smoking Service:** 0.5 mg (white tablets) twice daily
Duration of treatment	The normal treatment course is 12 weeks
Quantity to supply/administer	• Clients should be supplied a 14 day initiation pack and should set a quit date 7 to 14 days after initiation • Clients should be seen weekly (by the Stop Smoking Service) for at least 4 weeks after the quit date, then fortnightly • Only 14-day prescription packs should be used throughout the quit attempt

Instructions on identifying, managing & reporting adverse drug reactions	• For clients experiencing mild adverse effects after dose increase to 1mg twice daily, and where this is interfering with the quit attempt, consider a temporary or permanent dose lowering to 0.5 mg twice daily. (See BNF) Review at next scheduled appointment. • Smoking cessation with or without treatment is associated with various symptoms (see BNF **Cautions/Need for further advice)**. 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. • No attempt has been made in either the design or the analysis of the veranacline studies to distinguish between adverse events associated with study drug treatment or those possibly associated with nicotine withdrawal. • Clients should be asked at every appointment about their mood. 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 Service Provider. • If the client, family or care givers have concerns about agitation, depressed mood or changes in behavior, varenicline should be stopped immediately. Please refer to current BNF and SPC for full details. **The pharmacist is required to report all adverse reactions to the CSM via yellow card system.**

Side effects	Always refer to the current BNF and Summary of Product Characteristics (SPC) available from: www.medicines.org.uk. The most common adverse effects are: • Nausea is the most common side effect (about 30% of patients). This can be reduced by taking the tablet after food and with a full glass of water. • Sleep disorders/ abnormal dreams • Headache • Appetite changes • Dry mouth /taste disturbances • Drowsiness • Dizziness • Abnormal thinking • Mood swings (but see pages 7 and 8, **Cautions/Need for further advice)** See Latest BNF or Varenicline SPC for less common side effects www.medicines.org.uk Use the Yellow Card system to report adverse drug reactions (ADRs) directly to the Medicines and Healthcare Products Regulatory Agency (MHRA). Yellow cards (and guidance) are available in the back of the BNF or obtained via Freephone 0808 100 3352 or online at www.yellowcard.mhra.gov.uk. Report all significant ADRs to patient's own GP (with patient consent) **(Appendix 3).**

Advice to patient	• Advise client to read Manufacturer's Patient Information Leaflet • Please supply and advise client to read Patient Information Sheet Advice to clients should include specific product advice on dosage, method of administration and side effects. Clinicians should be aware of the possible emergence of depressive symptoms in patients undertaking a smoking cessation attempt and advise patients accordingly. Patients should be advised to seek medical advice if symptoms occur. It is important that client be encouraged to declare any current or history of mental illness (see information on exclusion criteria). Pharmacists should be aware of the possible stigma associated with the declaration of such conditions and therefore ensure that the client has sufficient privacy during the initial consultation to facilitate such conversations.

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It is important to make sure that the client understands the following points:
1. Varenicline is not a ***magic cure***: effort and determination are crucial;
2. It works by acting on the parts of the brain which are affected by nicotine in cigarettes;
3. It does not remove all the temptation to smoke, but it does make abstinence easier (it takes the edge of the discomfort by reducing the severity of tobacco withdrawal symptoms such as craving to smoke, irritability, poor concentration and low mood)
4. Varenicline is safe, but about a third of clients may experience mild nausea usually about 30 minutes after taking it. This reaction often diminishes gradually over the first few weeks, and most patients tolerate it without problems.

The following general advice should also be given:

- Follow-up and obtaining further supplies
- Possible changes in the body on stopping smoking e.g. weight gain
- **Varenicline may cause drowsiness**. If affected the patient should be advised not to drive or operate machinery
- Patients on insulin should monitor blood glucose closely
- If the patient forgets to take Varenicline, they should not take a double dose to make up for the one they missed. It is important they take the medication regularly and at the same time each day. If they have forgotten to take a dose, they should take it as soon as they remembered but if it is almost time for the next dose they should not take the tablet they have missed
- At the end of treatment, discontinuation of Varenicline has been associated with an increase in irritability, urge to smoke, and/or insomnia in up to 3% of patients. The pharmacist should inform the patient accordingly and discuss or consider the need for dose tapering.

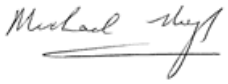
The major reasons for Varenicline failure are:
- Unrealistic expectations;
- Lack of preparation for the fact that tablets may cause nausea;
- Insufficient support from trained smoking cessation advisor
-poor patient compliance

Arrangements for medicine supply	The **Varenicline** should be dispensed from the community pharmacy stock labelled and recorded on the Patient Medical Record system. The client should be given a Patient Information Sheet as well as the Manufacturer's Patient Information Leaflet for **Varenicline**.
Storage requirements	The usual community pharmacy storage of medicines requirements apply.
Follow up	Clients will be seen by the Stop Smoking Advisor weekly for at least 4 weeks after the quit date and by the pharmacist at each supply of Varenicline. • Criteria for the stopping Varenicline treatment immediately: o The client does not want to continue treatment. o The stop smoking advisor or pharmacist believes that Varenicline treatment is no longer appropriate. o An absolute contra-indication is brought to light or develops. o A client develops agitation, depressed mood, suicidal thoughts or other serious mood changes (client to be referred to GP for prompt medical advice **(Appendix 3)** o Side effect is so severe as to impair quit attempt
Informed consent	Client must be informed that information relating to the supply of Varenicline under a PGD needs to be passed to other health service organisations, in particular their GP and Smoking Cessation provider to ensure proper record keeping and patient safety. Any information about clients will be stored securely. Information will be recorded on the assessment form **(Appendix 1)**

This patient group direction must be agreed to and signed by all health care professionals involved in its use.

Leicester City Council, Leicestershire County Council and Rutland County Council will hold the original signed copy.

The PGD must be easily accessible in the clinical setting

PATIENT GROUP DIRECTION WORKING GROUP		
NAME	**POSITION**	**SIGNATURE**
Zaheera Chatra	**Stop Smoking Service Manager** **Leicestershire County Council**	
Dr. Mike McHugh	**Consultant in Public Health (Leicestershire and Rutland County Councils)**	
Luvjit Kandula		

PATIENT GROUP DIRECTION CONTRIBUTORS		
Name	**Position**	**Signature**
Aaron Bohannon		

This PGD is approved for use within the area covered by Leicester City Council, Leicestershire County Council and Rutland County Council.

PGD Authorisation and Adoption by Leicester County Council

Director of Public Health Leicestershire County Council	Name Mike Sandys
	Signature
	Date

Responsibility for updating the PGD

Leicestershire County Council	Public Health commissioners will review the Service Specification to update the PGD.

Appendix 1

Individual Authorisation

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY

Pharmacy Details	
Name	
Address	
Telephone Number	

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

Note to Authorising Managers:
Authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.
Pharmacists should sign the table and keep their personal copy of this document.

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

I also declare that I am aware that I have an obligation to keep my practice and knowledge up to date and to respond to any changes that affect the content of this PGD and any changes in the use of PGDs in general.

Name of Professional	Signature	GPhC No	Authorising Manager/ Superintendent (if appropriate)	Date

Appendix 2

Leicestershire County Council- Assessment to supply Varenicline (Champix)
Criteria for Exclusion: ***Please complete the table with an (X) in the appropriate column***

Client Name		**Sensitive to Varenicline or any excipients?**	**Yes**	**No**
Date of birth		**Is the client pregnant?**		
Voucher no		**Is the client breastfeeding?**		
GP name and address		**Is the client under 18 years old?**		
Ethnicity		**Does the client have renal impairment?** ***Further information***		
Allergies (Please list type of reactions)		**Does the client have epilepsy or has been diagnosed by a seizure disorder?** ***Further information***		
Client's current medications		**Does the client have a history of low moods/ depression?** ***Further information***		
Access to client's records- consent given	Consent obtained: Yes/ No	**Has the client been prescribed medication for low moods/ depression?** ***Further information***		
Client signature and date:		**Does the client have an eating disorder?** **Further information**		
Pharmacist name: **GPhC**		**Does the client have a history of bipolar?**		

registration number: **Signature:** **Date:**		***Further information***		

<u>If the client has answered yes to the above criteria</u>: <u>Offer the option of NRT refer to Stop Smoking Service</u>

Appendix 3

Additional Guidance for Pharmacists

Referral Proforma

Patient Group Direction –Referral by Community Pharmacist to GP

Dear Doctor,

The named client below is considered to be unsuitable for issue of Varenicline under the Leicestershire County & Rutland County Council's Patient Group

Clients name	
Date of Birth	
Date and time of consultation with Pharmacist	

Appendix 4

Patient information leaflet-to be confirmed