

## STANDARD OPERATING PROCEDURE (SOP)

### Issuing of Varenicline e-voucher by a Yorkshire Smokefree Advisor and supply of varenicline by pharmacy professional through PGD

#### SECTION 1

| Version | Date     | Author                                                                                                                               | Status  | Comment |
|---------|----------|--------------------------------------------------------------------------------------------------------------------------------------|---------|---------|
| Draft 1 | 20/2/14  | Simon Lister<br>Yorkshire Smokefree<br>Service Manager                                                                               |         |         |
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| Draft 3 | 20/11/20 | Jan Spence<br>Yorkshire Smokefree<br>Service Manger                                                                                  |         |         |
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|-----------------------|------------|-------------|
|                       |            |             |

#### 1. Purpose

The purpose of this SOP is to enable the issue of an e-voucher and the supply of Varenicline to appropriate clients attending the Yorkshire Smokefree Service (YSF).

The rationale for supplying products via a voucher is to provide greater access to Varenicline. Varenicline, which is a prescription only medicine, will be supplied by community pharmacies via a Patient Group Direction (PGD).

#### 2. Scope

This SOP covers all stop smoking specialists and advisors working for the Yorkshire Smokefree Service.

Only clients receiving stop smoking support from the Yorkshire Smokefree Service may be issued with a Varenicline voucher.

This SOP also acts as guidance to community pharmacy professionals that have signed the YSF Varenicline PGD and are contracted to supply varenicline through the service level agreement with YSF.

**This is not a complete SOP for the pharmacy professional, it aims to make clear the responsibilities of the pharmacy professional, and the role of the advisor.**

### 3. Applicable Regulations and Policies



FINAL PGD -  
Varenicline - Barnsley

### 4. Who will Undertake the Procedure

All stop smoking specialists and advisors working for, or subcontracted to the Yorkshire Smokefree Service, who have completed the Level 2 or Intermediate Stop Smoking Skills Training will carry out the initial suitability assessment with the client.

Community pharmacy professionals that have signed the YSF Varenicline PGD and are contracted to supply varenicline through the service level agreement with YSF.

### 5. Procedure (advisor and pharmacy professional)

- I. Check the client's identification (name, date of birth, address) against the record on QuitManager.
- II. Inform the client that information relating to the supply of Varenicline under the PGD will be passed to their GP to ensure patient safety. This information will be sent by the pharmacy professional that supplies varenicline. Check that the client consents to this and consent is recorded on QuitManager (QM). If the client declines consent to contact their GP, a voucher cannot be issued.

### III. Eligibility to receive a voucher for varenicline

Advisor and pharmacy professional must check the client's eligibility against the inclusion and exclusion criteria of the PGD below. The advisor is performing an initial suitability assessment, but it is the pharmacy professional that will decide whether the client is suitable to receive varenicline via the PGD. The client must be informed of this by the advisor. The advisor and the pharmacy professional must complete the relevant checklist on Quitmanager.

**Please note it is the pharmacy professional's responsibility to check the inclusion/exclusion criteria. The pharmacy professional carries the legal responsibility for the supply of Varenicline under the PGD.**

| <b>Varenicline Voucher Inclusion Criteria (Answers must be YES to all)</b> |
|----------------------------------------------------------------------------|
| Age 18 years or above                                                      |
| Tobacco users sufficiently motivated to quit                               |
| Attending a Yorkshire Smokefree service                                    |
| Consent to share information with the client's GP                          |

## **Varenicline Voucher Exclusion Criteria (answers must all be NO)**

**Is varenicline contraindicated/not recommended for any of the following reasons:**

If the answer to any of the questions is **YES**, a voucher **CANNOT BE ISSUED**

- Client under 18 years
- Pregnant/trying to conceive or breastfeeding
- Hypersensitivity to varenicline or any excipients
- Epilepsy, fits or seizures
- End stage kidney disease
- Unable to swallow/absorb oral tablets
- Previous experience of serious or worrying side effects from varenicline
- Receiving varenicline or any other stop smoking treatment from GP
- Client taking clozapine

**Varenicline cautions** (drugs that may need a dose reduction due to stopping smoking)

- Patient taking warfarin/theophylline /aminophylline      Yes/No
- Patient taking olanzapine/erlotinib/rifampicin              Yes/No

**If YES to any of the medications above in varenicline cautions, the advisor must:**

- 1) send a letter by secure email to the prescriber of the medication e.g. theophylline, informing them that their patient intends to stop smoking and the drug may require monitoring and dose adjustment (see appendix for letter).
- 2) Inform the client that they must also contact their GP and tell them that they are stopping smoking and willing to attend for any monitoring required.

If the client agrees to contact their GP, the advisor may issue the voucher. **If not, the voucher cannot be issued.** If a voucher is issued, let the client know that it will be the pharmacy professional that will make the decision based on their clinical knowledge.

**When the e-voucher is presented at the pharmacy,  
The pharmacy professional must:**

- 1) Check that the client understands that a medicine they are taking might be affected by stopping smoking. Check the client has contacted their GP to let them know of their intention to quit, and that their GP is willing to monitor and adjust their dose of the affected drug if necessary.
- 2) Make the clinical decision whether to supply varenicline
- 3) If a supply is made, ensure the client knows any symptoms that may indicate they need to contact their GP (increased side effects and signs of toxicity)
- 4) If a supply is made, inform the GP within 48 hours.

**Varenicline cautions** (advisor and pharmacy professional)

- Cardiovascular disease-advise patient to contact GP if any worsening of symptoms
- Current or history of psychiatric illness-if client receives varenicline, ask about any changes in mood/behaviour and any suicidal thoughts at each follow up appointment and refer to GP if appropriate. Document on QM record
- Patient using insulin- give usual advice regarding monitoring of blood glucose levels whilst quitting
- Renal impairment -Pharmacy professional may give varenicline at reduced dose or decide not to supply.

**(pharmacy professional, see also sections 2.8 and 4.7 of varenicline PGD)**

**The patient information leaflet that will have been given to the client will give useful information on the above**

- IV. Inform the client how to take Varenicline i.e. explain how to use the titration and maintenance packs, that clients should plan to quit within 1-2 weeks of starting varenicline, each tablet should be swallowed whole with plenty of water, and can be taken with or without food (although experience would suggest after food is better and reduces nausea in those affected)
- V. If the client forgets to take varenicline they should not take a double dose to make up for a forgotten tablet. It is important to take varenicline regularly at the same time each day. If a dose is forgotten, take it as soon as remembered. If it is within 3-4 hours before the next dose, do not take the tablet that has been missed.
- VI. Discuss possible side effects.
- VII. Advise the client to read the product information leaflet prior to commencement of treatment.
- VIII. **Advisor-** Generate an e-voucher on QM this will be sent directly to the client's phone via an SMS or given verbally to the client. State on the voucher whether the client requires the titration or maintenance pack (see table below). The treatment regime is detailed below. For clients who cannot tolerate the full dose of varenicline (1mg) because of adverse effects e.g. nausea, the dose can be temporarily or permanently lowered to 0.5mg twice a day as per the Summary of Product Characteristics (SPC). The rationale for dose reduction should be documented on QuitManager.

| Pack                                                          | Day                         | Dose                              | Supply per voucher |
|---------------------------------------------------------------|-----------------------------|-----------------------------------|--------------------|
| Titration pack                                                | 1-3                         | 0.5mg (white tablets) once a day  | 11 tablets         |
|                                                               | 4-7                         | 0.5mg (white tablets) twice a day |                    |
|                                                               | 8-14                        | 1mg (blue) twice a day            | 14 tablets         |
| Maintenance pack                                              | 15 to 28                    | 1mg (blue tablets) twice a day    | 28 tablets         |
| Maintenance pack                                              | 29 to end of treatment      | 1mg (blue tablets) twice a day    | 56 tablets         |
| Maintenance pack for clients who cannot tolerate the 1mg dose | 1 or 15 to end of treatment | 0.5mg (white tablets) twice a day | 56 tablets         |

- IX. Vouchers will be issued to a maximum total of 12 weeks i.e. 4 vouchers per client

### **Nominal treatment regime:**

- Supply 1 - Two weeks titration pack
- Supply 2 - Two weeks (1mg x 28 tablets)
- Supply 3 – Four weeks (1mg x 56 tablets)
- Supply 4 - Four weeks (1mg x 56 tablets)

If the client requires a dose reduction to 0.5mg due to side effects. In total the treatment programme must not exceed 12 weeks.

- X. Inform the client of the participating pharmacies (also shown on the YSF website) where the voucher can be redeemed **and that they must attend the same pharmacy for all supplies of Varenicline. In exceptional circumstances e.g. where a pharmacy has a locum who is unable to supply under the PGD the client may access another pharmacy**
- XI. Varenicline will be supplied by the pharmacy professional in line with the Varenicline PGD.

### **6. Side effects**

Mild side effects include nausea, vomiting, GI discomfort, diarrhoea, dyspepsia, constipation, increased appetite, somnolence, flatulence, dizziness, headache, drowsiness, dry mouth and fatigue  
Severe side effects include chest pain, psychosis and suicide ideation.

For more detail on the potential side effects of Varenicline visit-  
[Varenicline](#) | [Drugs](#) | [BNF](#) | [NICE](#)

### **7. Counselling Points**

Varenicline may be linked with dizziness, sleepiness and transient loss of consciousness. Advise the client not to drive, operate complex machinery or engage in any other potentially hazardous activities until they know whether it affects their ability to perform these activities

### **8. Adverse Reaction Procedure**

Compliance and adverse reactions will be monitored at the weekly client follow-up appointment.

Mild adverse reaction such as persistent nausea/vomiting that cannot be tolerated by the client even after dose reduction to 0.5mg from 1.0mg twice daily will be recorded in the client record and the client will be advised to stop taking Varenicline and to consider Nicotine Replacement Therapy or bupropion.

Severe adverse reactions such as suicide ideation will be recorded in the client record and reported to the Yorkshire Smokefree Service Manager (or deputy) immediately. The client will be advised to stop taking varenicline immediately and to see their GP as soon as possible. The Service Manager

will investigate the incident and contact the clients GP if necessary. The incident will be escalated through the Trusts incident reporting system and reported to the clients GP.

Staff will report any adverse reactions in accordance with the UK Adverse Drug Reaction Reporting Guidelines (Yellow card system available at: <https://yellowcard.mhra.gov.uk/>)

## 9. Follow-up Advice

Clients will be seen by the Stop Smoking Advisor weekly for at least 4 weeks after the quit date and by the pharmacy professional at each supply of Varenicline. Clients should be advised to call their local Yorkshire Smokefree Service if they need support or advice in addition to the weekly appointment.

Criteria for stopping Varenicline treatment immediately:

- The client does not want to continue treatment.
- The stop smoking advisor or pharmacy professional believes that varenicline treatment is no longer appropriate.
- An absolute contra-indication is brought to light or develops.
- The client develops agitation, depressed mood, suicidal thoughts or other serious mood changes (client to be referred to GP for prompt medical advice)
- Side effect is so severe as to impair quit attempt

## 10. Definitions

QuitManager is the Yorkshire Smokefree Service dedicated electronic client record.

## Appendices



GP letter FINAL.docx SC FINAL letter.docx