

**ABL Health Ltd**

**Service Level Agreement**

**for the Provision of Varenicline**

**by Community Pharmacists in**

**Nottinghamshire**

 **Version: 1**

 **Date: 30th April 2020**

**Introduction**

National context

The Tobacco Control Plan for England (2017-2022) has set out the following national targets:

* Reduce the inequalities between those working in routine and manual occupations and the general population caused by smoking by the end of 2022
* Reduce the prevalence of smoking among adults to less than 12% by the end of 2022
* By the end of 2022 the prevalence of smoking in pregnancy should be reduced from 10.7% to 6% or less
* Reduce the prevalence of smoking in young people under the age of 15years to 3% or less by 2022

There is an overarching target of reducing the prevalence of smoking in England to 5% or less by 2030

This Service Level Agreement (SLA) relates to the provision of Varenicline (Champix) for adults over the of 18years by pharmacists in Nottinghamshire and will support the structured treatment plan agreed by the client and the Specialist Stop Smoking Service. The purpose of the service is to reduce the prevalence of smoking by targeting priority groups, ultimately reducing the health inequalities throughout the county.

Pregnant women and those under the age of 18years are exempt from this SLA (see inclusion and exclusion criteria cited the PGD).

The Specialist Stop Smoking Service supports tobacco users throughout the county on Nottinghamshire. Therefore, to ensure clients have easy access to Varenicline pharmacists across the county will be accredited through their Declaration of Competence and training as required.

The National Institute of Care Excellence and the NCSCT cite that outcomes for stopping smoking are better when medication and professional support is used together.

There are 4 generally accepted MHRA approved medications that tobacco

users may use to help them to quit. Varenicline is one of these.

**Summary of NICE guidance:** Varenicline is recommended within its licensed indications as an option for smokers who have expressed a desire to quit smoking. Varenicline should normally be prescribed only as part of a programme of behavioural support.

The Specialist Stop Smoking Practitioners will assess smokers who request are eligible to use prescription only medication (POM) Varenicline as part of their overall treatment plan. This being agreed, a letter of recommendation will be given to the client to take to a participating pharmacy within the County of Nottinghamshire.

The pharmacist will complete their own assessment for suitability against the PGD inclusion and exclusion criteria and the Summary of Product Characteristic (SPC) indications and contra-indications, then the prescription will be filled.

**Premises requirements:**

* The pharmacies will be based in a variety of locations across the county and are easily accessible and suitable for eligible service users.
* Service provision must be conducted in a safe, suitable premises for a private consultation where potentially sensitive questions may be asked and not overheard.
* The pharmacy must be Disability Discriminatory Act (DDA) compliant.
* The pharmacy must have access to an electronic recording system to record client intervention information securely and claim reimbursement.

**Pharmacist requirements:**

All pharmacists are bound by guidelines in their Code of Ethics maintain client confidentiality, privacy and dignity at all times. This is reiterated in the statement from the Royal Pharmaceutical Society, “show respect for others”.

Pharmacists supplying Varenicline via the PGD must meet the following requirements.

* Be working in a suitable pharmacy with a consultation room.
* Will enable provision of Varenicline within 48 hours (maximum timeframe) of being contacted by the client or Specialist Stop Smoking Practitioner of the client`s recommendation.
* Will ensure that their professional indemnity cover confirms that the activity for providing Varenicline under the PGD is included.
* Will be a registered member of the General Pharmaceutical Council (GPhC)
* They must be registered with the Centre for Pharmacy Postgraduate Education (CPPE).
* Demonstrate their competencies for supplying Varenicline via the PGD through completing the CPPE Declaration of Competence (DoC). This will provide reassurance that a system of clinical governance is in place. A standard operating procedure (SOP) must be in place for this service and will support the clinical governance.
* Ensure an agreed system is in place to submit reports of client safety incidents to ABL Health.
* Completed the online NCSCT training on Brief Intervention and smoking cessation medication ([www.ncsct.co.uk](http://www.ncsct.co.uk)) and PGD training as appropriate.
* It is the responsibility of the participating pharmacist to assess the clients

 suitability against the PGD inclusion and exclusion criteria and the SPCs

 indications and contra-indications

* Liaise with other healthcare professionals and ABL Health Ltd Stop Smoking Service Practitioners when necessary
* Will supply Varenicline in accordance to the PDG.
* Will comply to the Equality Act 2020.
* Keep accurate records for payments and submit via the electronic Pharma outcomes system 4 weekly (TBC)

**Volume:**

It is anticipated that over 1,500 clients will request and be suitable for Varenicline each year, some of whom may not complete the full course.

**Referrals and description of treatment**

Varenicline must only be supplied to clients who are being supported by ABL Health Specialist Stop Smoking Practitioners. The client must have consented to receive regular support and have set a quit date.

 With their Specialist Stop Smoking Practitioner the client will develop a treatment plan.

 Should Varenicline form part of the client`s treatment plan, having been

 assessed by the Stop Smoking Practitioner, they will receive a letter of

 recommendation to take to a participating community pharmacist for

 a supply of the medication. The letter of recommendation will contain the clients unique

 service ID number. **(Appendix 1)** All client`s records must carry this number.

 The pharmacist will provide an appointment within 48hours of being contacted by the

 client or the Specialist Stop Smoking Service.

 The client will be advised to attend the same pharmacist through their regime to ensure

 continuity of care.

 The quantity of Varenicline issued must comply to the PGD.

 The treatment regime is described in the PGD and the pharmacist should inform clients

 the reasons for Varenicline not resulting in an unsuccessful quit are:

* Unrealistic expectations
* Lack of understanding of the fact that the medication may cause nausea and /or disturbed sleep (vivid dreams)
* Insufficient or incorrect use

It is important that the client understands that:

* Varenicline is safe
* Varenicline is not a magic cure
* It works on the part of the brain which is affected by nicotine
* It does not remove all the temptations to smoke

**Inclusion and exclusion:**

Before supplying Varenicline the pharmacist must complete the inclusion and exclusion proforma. **(Appendix 2)**

If the pharmacist has any concerns about the suitability of a client who has been referred, they must inform the referring Specialist Stop Smoking Practitioner within 1 working day.

Pharmacists must provide instruction on the correct use / daily dosage. In all circumstances dosing should follow the recommendations in the Varenicline Summary of Product Characteristics <http://www.medicine.org.uk/emc>

Clients should be supplied with a 14 - day initiation pack and set a quit day 7-14 day after starting the medication. 14 - day prescription packs only must be supplied, complete with the patient information leaflet (PIL) throughout the quit attempt. The normal course is for 12 weeks. A record of issue must be kept. **(Appendix 4)**

Letters for the request for the follow up 2 weekly supplies will be issued to the client from the Specialist Stop Smoking Practitioner to take to the Pharmacist. **(Appendix 5)**

There may circumstances clients may be issued with 1 month`s supply, for example if they are going on holiday or are working away and are unable to attend face to face support with their Specialist Stop Smoking Practitioner for that time.

In exceptional cases some clients may need part, or all, of an additional course of Varenicline. This will be with the agreement of the Specialist Stop Smoking Service Lead or Head of Smoking Cessation Services. The maximum length of treatment is 24 weeks.

**Communication:**

**Pharmacists must obtain clients written consent to contact a third party this includes their GP. It may be necessary for the pharmacist to contact the GP for the client`s medical history to enable an informed decision about initiating Varenicline. (Appendix 3)**

**If the client declines consent to information sharing, it will not be possible to issue a supply of Varenicline under the PGD.**

The pharmacist must inform the clients GP within 2 working days that an initial supply of Varenicline has been made in accordance to the PGD.

Where dose adjustments of other current prescribed medication are required the client must be advised to contact their GP or other relevant Healthcare Professional.

If a GP informs the pharmacist that the client should not receive Varenicline as a result of the notification correspondence, the pharmacist must contact the client immediately.

The pharmacist must refer the client back to the Specialist Stop Smoking Service to discuss and access alternative treatment which would include Nicotine Replacement Therapy (NRT) by Direct Supply. This must be recorded in the client`s records.

**Adverse Drug reactions (ADRs)**

The Medicines and Health Product Regulatory Agency (MRHA) requests that all suspected reactions are reported through the Yellow Card scheme (including those not considered serious). ADRs can be reported online: [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk) or via the yellow card which is cited at the back of the current BNF.

**Documentation and database**

All necessary forms and documentation onto the database must be completed accurately and in a timely manner.

Invoices must be submitted to ABL Health LTD at one monthly intervals.

**Contract price and payment schedule**

The following payments will be made to the contractor for the delivery of this service upon receipt of the monthly claims. Reimbursement for the drug costs must be submitted monthly.

|  |  |
| --- | --- |
| Intervention | Varenicline (18+) |
| First visit/referral | £14 |
| 2nd visit | £14 |
| Follow up visits x 4 | £8 |

**Appendix 1- Letter of recommendation from Specialist Stop Smoking Practitioner to the Pharmacist**

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**Nottinghamshire Integrated Wellbeing Service**

**ABL Health**

**Unit 50**

**Ransom Hall South**

**Ransom Wood Business Park**

**Mansfield**

**NG21 0HJ**

Tel: 01623 287810

www.yourhealthnotts.co.uk

email: yourhealthnotts.co.uk

Dear Pharmacist,

Client ID………………………

Client name………………………………….. DoB…/…/….

Address.……………………………………………………………………

GP Name / Practice……………………………………………………….

This client has accessed the Specialist Stop Smoking Service for help to stop smoking and have agreed to intensive, regular support by the service. They have set a quit date of …………….

To help with their quit they would like to use Varenicline. A discussion and assessment regarding their current and past health status, along with the disclosure of current medication, has been made during their initial consultation. Any contra-indications for them receiving Varenicline do not appear apparent.

Based on your assessment if you think it is appropriate for this client to continue with their quit attempt using Varenicline could you please issue them with an initiation pack of 2 weeks supply under the PGD.

Thank you for your assistance.

Yours sincerely

Specialist Stop Smoking Practitioner

**Appendix 2 - Client Assessment Proforma for Varenicline (Champix)**

**Client ID no………………..**

**Pharmacy stamp**

**Clients name:**

**DOB:**

**Address:**

**Telephone number:**

**GPs name and Address:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Exclusion criteria** | **Yes**  | **No** | **Action** |
| Hypersensitivity to Varenicline or its excipients  |  |  | If yes, refer back to the Specialist Stop Smoking Service for alternative therapy |
| History of renal impairment or end stage renal disease or undergoing investigations |  |  | If yes, refer back to the Specialist Stop Smoking Service to consider alternative therapy |
| Suffer from epilepsy or has a history of convulsions/taking anti-epileptic medication or other conditions which lower the seizure threshold |  |  | If yes refer back to the Specialist Stop Smoking Service for alternative therapy |
| Experienced serious or concerning adverse effects from a previous course of Varenicline  |  |  | If yes refer back to the Specialist Stop Smoking Service for alternative therapy |
| Pregnant or breastfeeding or trying to conceive |  |  | If yes refer back to the Specialist Stop Smoking Service for alternative therapy |
| Presently suffers from unstable cardiovascular disease |  |  | If yes refer back to the Specialist Stop Smoking service for alternative therapy |
| Using other forms of licensed NRT or another smoking cessation medication |  |  | If yes, decline and refer back to the Specialist Stop Smoking Service |
| Unstable psychiatric illness:Schizophrenia, psychosis, bipolar disorder or severe depression *(****short term depression is not a contra-indication for exclusion)*** |  |  | If yes, refer back to the Specialist Stop Smoking Service for alternative therapy |
| Is not registered with a Nottinghamshire GP Practice |  |  | Refuse and ask them to register |
| Does not provide consent |  |  | Decline treatment |
| Does not offer valid consent to share information with their GP |  |  | Decline treatment and refer back to the Specialist Stop Smoking Service |
| Is under the age of 18 years |  |  | If yes, refer back to the Specialist Stop Smoking Service |

Action taken:

Supply issued: Yes No

Referred to Specialist Stop Smoking Service: Yes No

The action specified was based on the information given to me by the client.

Pharmacist name:

Pharmacist signature:

Date:

The information I have provided to the pharmacist is to the best of my knowledge. They have provided me with an informed choice, and I understand the advice given to me by the pharmacist.

**Clients signature:**

**Date:**

**Appendix 3 - Notification to a GP that Varenicline has been initiated by an authorised Nottinghamshire Pharmacist**

**Nottinghamshire Integrated Wellbeing Service**

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**Unit 50**

**Ransom Hall South**

**Ransom Wood Business Park**

**Mansfield**

**NG21 0HJ**

Tel: 01623 287810

www.yourhealthnotts.co.uk

email: yourhealthnotts.co.uk

Dear Dr……..

Re: Clients name…………………………………. DoB…………………

Address…………………………………………………………………………….

Client ID………………………..

The above client was referred to me by the Specialist Stop Smoking Service in accordance with the PGD for Varenicline.

I have taken a medical history to ascertain that they do not have contraindications or risk factors for taking Varenicline, and therefore meet the criteria for the supply under the PDG. The use of medication and possible side effects have been explained to the client to which they agree to understand. They will be supported by a Specialist Stop Smoking Practitioner throughout their quit attempt and will be issued with Varenicline at 2 weekly intervals for up to 12 weeks.

If you do not agree that this client should be issued with Varenicline could you please contact me as soon as possible. Alternatively, I would be grateful if you could add this medication to the client`s medical records.

Yours Sincerely

Print name

Pharmacist

**Appendix 4 - Record of Standard Supply of Varenicline under the PGD**



Client ID……………………………..

Client name……………………………………………………..

|  |  |
| --- | --- |
| Date:Pharmacist name:Signature: | Supply: Initiation pack 25 tablets |
| Date:Pharmacist name:Signature: | **Post quit date:**Supply: 2-week maintenance pack (28 tablets)Dose: |
| Date:Pharmacist name:Signature: | Supply:2-week maintenance pack (28 tablets)Dose: |
| Date:Pharmacist name:Signature: | Supply:2-week maintenance pack (28 tablets)Dose: |
| Date:Pharmacist name:Signature: | Supply:2-week maintenance pack (28 tablets)Dose: |
| Date:Pharmacist name:Signature: | Supply:2-week maintenance pack (28 tablets)Dose: |

**Appendix 5 - Letter of recommendation for the continuation of Varenicline post initiation pack**



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Dear Pharmacist

Client ID…………………………………

Client name……………………………………. DoB……………………

Address……………………………………………………………………………….

This client has successfully stopped smoking and would like to continue to use Varenicline to support their quit attempt. They have not disclosed any adverse effects from the medication.

Could you please provide them with a further supply of Varenicline, weeks… and …… under the PGD?

Yours sincerely

Specialist Stop Smoking Practitioner.