

# NEWCASTLE CITY COUNCIL

## PUBLIC HEALTH SERVICE SPECIFICATION

<b>Service</b>	Supply of Varenicline within Pharmacies under a Patient Group Direction
<b>Commissioner Lead</b>	Louise Lane
<b>Provider Lead</b>	Pharmacies who are signed up to the relevant Patient Group Direction
<b>Period</b>	September 2019 – July 2021

<b>1.</b>	<p><b>Overall purpose of service</b></p> <p>The aim of this service is for Varenicline to be prescribed via a Patient Group Direction using a voucher scheme, as part of the commissioned stop smoking service.</p> <p>To ensure patients who are smokers have an accessible treatment service to help them to stop smoking. This pharmacy-based service will help to increase choice and improve access to stop smoking medication. It will contribute to local public health and tobacco control strategies, which have a commitment to reduce smoking and contribute to the targets measured by the number of smokers who stop.</p> <p>NICE has made recommendations for the use of Varenicline for smoking cessation.</p>
<b>2.</b>	<p><b>Expected outcomes for service</b></p> <p>Varenicline is licensed as an option for smokers who have expressed a desire to quit smoking. Varenicline can only be supplied under a Patient Group Direction (PGD) or Patient Specific Direction (PSD).</p>
<b>3.</b>	<p><b>Evidence base for the service</b></p> <ul style="list-style-type: none"> <li>• <a href="#">QS43 Smoking cessation: supporting people to stop smoking</a> (NICE, 2013)</li> <li>• <a href="#">PH10 Smoking cessation services</a> (NICE, 2008)</li> <li>• <a href="#">TA123 Smoking cessation – varenicline</a> (NICE, 2007)</li> </ul>
<b>4.</b>	<p><b>Selection of Service</b></p> <p>The Pharmacies for this service will be selected the commissioners of the service to provide an adequate geographical spread across Newcastle upon Tyne.</p>
<b>5.</b>	<p><b>Scope of Service</b></p> <p>Varenicline is prescribed only as a component of smoking cessation support programme. Treatment should be limited to 12 weeks and prescribing intervals should be short and dependent upon continual attendance at treatment clinics.</p> <p>Only one treatment episode of Varenicline (up to 12 weeks) can be offered in a six month period and the patient must remain abstinent from smoking after their quit date (between day 8 and 14). Payment maybe withheld by the Local Authority if this is not adhered to.</p> <p>Patients who already have previously quit using Varenicline in the same year and relapsed cannot be offered Varenicline treatment again until six months have passed since the last treatment started.</p>

### **5.1 Service description (including target group)**

Requirements for qualification as providers:

- Qualified Pharmacist
- Approved Premises
- Authorised by the local authority to prescribe Varenicline under the PGD
- Service is offered during opening times of the pharmacy

Key elements of Pharmacists prescribing Varenicline:

- The provision of stop smoking programmes in pharmacy should be for up to 12 weeks.
- Clients will be given weekly appointments with their stop smoking adviser for at least the first 4 weeks. Vouchers will be given to the client to take to an authorised pharmacy at two weekly intervals.
- The assessment tool attached to the PGD should be used where Varenicline has been suggested as smoking cessation product.
- Each supply of Varenicline should be for no more than 2 weeks, unless the patient has a planned holiday or absence from home.
- GPs should be notified of the commencement of this treatment within two working days.
- If you are prescribing Varenicline to a Client who has started their Stop Smoking journey with an Adviser other than yourself you must also notify the relevant Adviser that they have commenced treatment.
- Any significant adverse reactions noted by the patient must be acted on immediately, and medical advice sought.

### **5.2 Entry into service (referral routes)**

The only entry mechanism is by referral with a voucher from a trained and accredited stop smoking adviser. The Newcastle upon Tyne Voucher Scheme protocol and process map is appended to this service specification.

### **5.3 Exit from service (discharge criteria and planning)**

Smokers will be discharged from the programme by their stop smoking adviser. The pharmacy will receive a maximum of six varenicline vouchers, each for 2 weeks supply. Stop smoking advisers may terminate a client (normally for non-attendance or relapse) at any time during the programme. Pharmacies will be paid for vouchers provided by the smoking cessation service. This means that the full fee will only apply for those clients who complete the course.

### **5.4 Inclusion/exclusion criteria**

- Clients 18 years of age and over
- Nicotine users identified as sufficiently motivated to quit
- Nicotine users who are receiving support to stop smoking with a Newcastle upon Tyne contracted NHS Stop Smoking Service
- Client is resident in Newcastle upon Tyne or is registered with a Newcastle upon Tyne GP
- A medical history is taken and documented and there are no contraindications for treatment with varenicline and that any cautions for use are recorded.
- No indication on Pharmacy Patient Medication Record that the patient is unsuitable for Varenicline

Clients excluded from the PGD for the following reasons should be referred back to their stop smoking adviser with an explanation that the patient is unsuitable for varenicline:

- Tobacco users not sufficiently motivated to quit or use varenicline
- Clients under 18 years of age
- Sensitivity to varenicline or any of its excipients
- Pregnancy/ Breastfeeding
- Client already receiving varenicline prescribed by GP

	<ul style="list-style-type: none"> <li>• Renal impairment or end stage renal disease as decreased clearance by kidney increases side effects.</li> <li>• Substance misuse patients</li> <li>• Clients who have experienced serious or worrying side effects from a previous course of varenicline</li> <li>• PMR indicates that patient is unsuitable for Varenicline</li> </ul> <p>Patients who do not fit the PGD criteria because of:</p> <ul style="list-style-type: none"> <li>• Epilepsy or history of fits or seizures</li> <li>• active or history of severe and enduring mental illness should be referred to their GP for further advice. They may then be supplied with varenicline if the GP provides a PSD. The action taken must be documented.</li> </ul> <p>Clients who develop any serious adverse effects, including any signs of agitation, depressed mood, suicidal thoughts or other serious mood changes must be referred to GP for prompt medical advice. The pharmacist should contact the patients GP surgery and arrange an appointment for the client to see the GP.</p> <p><b>5.5 Interdependencies/Key Relationships</b> Patients GP and stop smoking adviser</p> <p><b>5.6 Location of service</b> Community Pharmacy</p> <p><b>5.7 Geographic coverage of service</b> All residents of Newcastle upon Tyne and those registered with a Newcastle upon Tyne GP.</p> <p><b>5.8 Service availability (opening hours)</b> Individual to pharmacy.</p>
6.	<p><b>Quality standards for services</b></p> <ul style="list-style-type: none"> <li>• The pharmacy has appropriate health promotion and service material available for users and promotes its uptake.</li> <li>• The pharmacy can demonstrate that pharmacists have completed all appropriate training.</li> <li>• The pharmacy can demonstrate that service and monitoring guidelines as stated here and in training, are followed throughout the provision of this service.</li> <li>• The pharmacy notifies the commissioners immediately if there is likely to be a disruption in the availability of the service – e.g. trained pharmacist leaves or goes on long term sickness absence.</li> <li>• If there is no trained pharmacist available, it is the responsibility of the pharmacy to find the client a pharmacy which can supply the service</li> <li>• The pharmacist participates in any organised audits of service provision and update training.</li> <li>• The pharmacy co-operates with any locally agreed led assessment of service user experience.</li> </ul>
7.	<p><b>Accessibility of service</b></p> <p>The provider will comply with the Equality Act 2010 in the provision of this service. The provider will work within the framework of the Newcastle City Council Equality Policy.</p>
8.	<p><b>Performance management framework</b></p> <p>The service provided in pharmacies is monitored by the return of Varenicline data via PharmOutcomes.</p> <p><b><u>Audit</u></b></p>

	<p>The Pharmacy must allow the Local Authority's internal and other nominated auditors access to all or any papers and relevant data relating to this agreement for the purposes of audit. The pharmacy must fully co-operate to carry out service evaluation audits.</p> <p>The Pharmacy must submit a yearly self-certification for the service to the Local Authority.</p>						
<p><b>9.</b></p>	<p><b>Price</b></p> <p>Each pharmacy contracted to provide this service will be paid:  £13 for initial assessment  £4 for each first review  £2 for each subsequent supply (max 4)</p> <p>In terms of drug costs, each Pharmacy will be paid the following amounts depending on the stage of Varenicline use</p> <table data-bbox="183 645 1165 750"> <tr> <td>First pack (Titration pack-mixture of 0.5mg and 1mg tablets)</td> <td>£27.30</td> </tr> <tr> <td>Maintenance pack (1mg tablets x 28)</td> <td>£27.30</td> </tr> <tr> <td>Maintenance pack (0.5mg tablets x 28)</td> <td>£27.30</td> </tr> </table> <p>Payment to pharmacies will be provided according to timely and complete data submitted via PharmOutcomes and will be paid on a quarterly basis.</p> <p>No payment will be made retrospectively for any part of this service conducted prior to 1<sup>st</sup> October 2015.</p>	First pack (Titration pack-mixture of 0.5mg and 1mg tablets)	£27.30	Maintenance pack (1mg tablets x 28)	£27.30	Maintenance pack (0.5mg tablets x 28)	£27.30
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