

NEWCASTLE CITY COUNCIL

PUBLIC HEALTH SERVICE SPECIFICATION

Service	Supply of Varenicline within Pharmacies under a Patient Group Direction
Commissioner Lead	Louise Lane
Provider Lead	Pharmacies who are signed up to the relevant Patient Group Direction
Period	Oct 2015 - Oct 2018.

1. Overall purpose of service

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.

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.

NICE has made recommendations for the use of Varenicline for smoking cessation.

2. Expected outcomes for service

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).

3. Evidence base for the service

- [QS43 Smoking cessation: supporting people to stop smoking](#) (NICE, 2013)
- [PH10 Smoking cessation services](#) (NICE, 2008)
- [TA123 Smoking cessation – varenicline](#) (NICE, 2007)

4. Selection of Service

The Pharmacies for this service will be selected the commissioners of the service to provide an adequate geographical spread across Newcastle upon Tyne.

5. Scope of Service

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.

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 & 14). Payment maybe withheld by the Local Authority if this is not adhered to.

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.

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 must 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 one working day.
- 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 if there is a delay to the client starting treatment of more than five days.
- 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. Clients who miss 3 full days of medication will not be supplied further and should be referred back to their stop smoking advisor. Pharmacies will be paid for vouchers provided by the smoking cessation service therefore 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 or working 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
- Renal impairment or end stage renal disease as decreased clearance by kidney increases side effects.
- Substance misuse patients
- Clients who have experienced serious or worrying side effects from a previous course of varenicline
- PMR indicates that patient is unsuitable for Varenicline

Patients who do not fit the PGD criteria because of:

- Epilepsy or history of fits or seizures or,
- Active or history of severe and enduring mental illness

may still be supplied with varenicline if the GP sends back a signed PSD (Appendix 3) i.e. pharmacists should send appendix 3 through to the GP who will sign and send back if authorising supply to the patient.

Note 1: Active or history of severe and enduring mental illness E.g. patients with bipolar disorder or schizophrenia will require a PSD (appendix 3).

All action taken must be documented.

Note 2: A question regarding medical history that stop smoking advisors will ask clients in advance of supplying a voucher for Varenicline is: "Do you know of any reason why you would not be suitable for a supply of Varenicline?" The responsibility of using appendix 1 rests with the pharmacist making the supply of varenicline against the PGD.

Note 3: PSD Appendix 3 - GP Consent: Pharmacists not receiving a response to the request for authorisation of a PSD within 5 days should contact the GP directly to establish the status of this application. In addition the smoking advisor who has written the voucher should be informed due to the delay in starting treatment."

Note 4: 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.

5.5 Interdependencies/Key Relationships

Patients GP and stop smoking adviser.

5.6 Location of service

Community Pharmacy.

5.7 Geographic coverage of service

All residents and those working in Newcastle upon Tyne and those registered with a Newcastle upon Tyne GP.

5.8 Service availability (opening hours)

Individual to pharmacy.

6. Quality standards for services

6.1 Promotion

- The pharmacy has appropriate health promotion and service material available for users and promotes its uptake.

6.2 Training

- The pharmacy can demonstrate that pharmacists have completed all appropriate training.

6.3 Dependability

- 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 or alternatively, if the pharmacist or stop smoking advisor is on holiday then up to three vouchers can be written in advance by the advisor in for this period for simultaneous supply in advance. It is still the discretion of the pharmacist as to whether to make the supply.
- If the client has a holiday planned then up to three vouchers can be written in advance by the advisor in for this period.

6.4 Communication

- 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. It is the pharmacy's responsibility to provide cover for the service in these circumstances i.e. both backup advisors and pharmacists. Locums / relief staff should be trained to cover planned absences – days off, holiday, etc.
- The client should present their voucher AND collect their first supply of medication within 5 days of the date on the written voucher number 1. If this is not the case then the advisor should be made aware.

6.5 Quality Assurance

- The pharmacy can demonstrate that service and monitoring guidelines as stated here and in training, are followed throughout the provision of this service.
- The pharmacist participates in any organised audits of service provision and update training.
- The pharmacy co-operates with any locally agreed led assessment of service user experience.
- If a client is referred to another pharmacy, the 'new' pharmacist needs to start the whole assessment process (starting with appendix 1) in order to comply with the PGD. Clients should ideally be maintained in one pharmacy.

6.6 Flexibility

- Occasionally, support may be continued for patients who remain smokers beyond the normal quit period of days 8 to 14. This should be only under exceptional circumstances where the patient has demonstrated a significant desire to stop smoking.

7. Accessibility of service

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.

8. Performance management framework

The service provided in pharmacies is monitored by the return of Varenicline data via PharmOutcomes.

Audit

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.

The Pharmacy must submit a yearly self-certification for the service to the Local Authority.

9. Price

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)

In terms of drug costs, each Pharmacy will be paid the following amounts depending on the stage of Varenicline use

First pack (Titration pack-mixture of 0.5mg and 1mg tablets)	£27.30+VAT
Maintenance pack (1mg tablets x 28)	£27.30+VAT
Maintenance pack (0.5mg tablets x 28)	£27.30+VAT

Payment to pharmacies will be provided according to timely and complete data submitted via PharmOutcomes and will be paid on a quarterly basis.

No payment will be made retrospectively for any part of this service conducted prior to 1st October 2015.