

## SPECIFICATION

<b>Service</b>	<b>Active Intervention NHS Stop Smoking Service</b>
<b>Council Lead</b>	<b>Joy Evans</b>
<b>Provider Lead</b>	<b>Pharmacist</b>
<b>Period</b>	<b>1<sup>st</sup> April 2017 – 31<sup>st</sup> March 2018</b>

### 1. Population Needs

#### **National/Local Context and Evidence Base**

Through Vision 2030 we have set our long term ambition vision for Gateshead “local people realising their full potential, enjoying the best quality of life in a healthy, equal, safe, prosperous and sustainable Gateshead.”

The Council Plan 2015-2020 sets out how we will achieve this vision over the next five years. As identified in the Council Plan, we are committed to achieving our Live Well Gateshead outcome of a healthy, inclusive and nurturing place for all and reducing our smoking prevalence will contribute to this.

The Joint Strategic Needs Assessment (JSNA) for Gateshead which assists in identifying the key features facing people in Gateshead was carried out in 2015. The JSNA identified key strategic priorities to improve the health and wellbeing of our population. The data identified that one in four adults in Gateshead smoke, which increases to one in three for those in routine and manual occupations. Local survey data highlights wide variations across Gateshead, with highest smoking rates in the most deprived areas.

Smoking is the single largest cause of preventable mortality in England. This is recognised in the Government’s Public Health White Paper ‘Healthy lives, healthy people’, which states that ‘reducing smoking rates represents a huge opportunity for public health.’

Reducing smoking prevalence is identified as a key outcome in the new Public Health Outcomes Framework and local prevalence remains above the national average. Smoking remains the single greatest contributor to health inequalities and premature death and disease in the North East with prevalence rates for adults in Gateshead at 18.3%% (2015) which is significantly higher than the England average of 16.9% (2015).

Healthy lives, healthy people: a tobacco control plan for England (March 2011) sets out how tobacco control will be delivered in the new Public Health system focusing in particular on driving down prevalence of smoking and support of tobacco control in local areas.

NICE guidance clearly identifies a number of effective stop smoking interventions for

everyone involved in, or responsible for stop smoking services, including brief intervention, individual behavioural counselling, group behaviour therapy, pharmacotherapy, self-help materials, telephone counselling and quit lines.

The Provider must work with the Council to deliver Services in line with all National Standards including:

- Healthy lives, healthy people: a tobacco control plan for England (March 2011)
- DoH Excellence in Tobacco Control – 10 High Impact Changes to Achieve Tobacco Control
- National Centre for Smoking Cessation and Training Local Stop Smoking Services: Services and delivery guidance (2014)
- Healthy lives, healthy people: Improving outcomes and supporting transparency – Public Health Outcomes Framework (January 2012)
- Healthy lives, healthy people White Paper: Update and way forward (July 2011)
- NCSCT Electronic cigarettes: A briefing for stop smoking services [http://www.ncsct.co.uk/publication\\_electronic\\_cigarette\\_briefing.php](http://www.ncsct.co.uk/publication_electronic_cigarette_briefing.php)

In recent years e-cigarettes have entered the market, and although they are 95% safer than tobacco, NHS stop-smoking services still provide the best chance of quitting.

## 2. Key Service Outcomes

Better health for Service Users:

- Longer life
- Better quality of life
- Reduced use of health services
- Fair access to services

Excellent Service User experience

- Safe care
- Efficient treatment
- High quality service
- Timely access to services
- Using your money wisely

## 3. Scope

### 3.1 Aims and objectives of the Service

The primary role of the Provider is to deliver a high quality stop smoking Service to the local population. The Service the Provider is to deliver must also contribute to a

reduction in harm from tobacco and to the achievement of local and national targets as outlined below:

- To contribute to the Council target of individuals stopping smoking at 4 weeks as set out in Schedule 2
- To provide smoking cessation services to 5% of local smokers each year
- To help reduce smoking prevalence to 5% in Gateshead by 2025
- To reduce smoking prevalence in the following priority groups; pregnant women, people with long term conditions or mental health problems, minority ethnic communities and young people, and those who are disadvantaged and most at risk of dying early from heart disease. Disadvantaged people include those who are living on a low income, those who are homeless and people with disabilities.
- To deliver high quality healthcare, value for money, local access to Services and a positive Service User experience

### **3.2 Service description**

The Provider must make the Service available to any smoker living or working in Gateshead who wishes to stop smoking or to reduce the amount they smoke.

#### **Advice**

The Provider must give very brief advice, based upon “Ask, Advise, Act”, to all known smokers unless inappropriate to do so.

#### **Active Intervention**

The Provider must deliver a stop smoking Service based on the active intervention model, using motivational interviewing and cognitive behavioural techniques. Stop Smoking support must be provided by Staff who are trained active intervention advisors and may be delivered in a variety of evidence based formats including but not exclusive to 1:1 support, group support (open and closed), and telephone or email interventions. The Service must be delivered by the Provider in line with the standards and techniques laid down in the active intervention training manual.

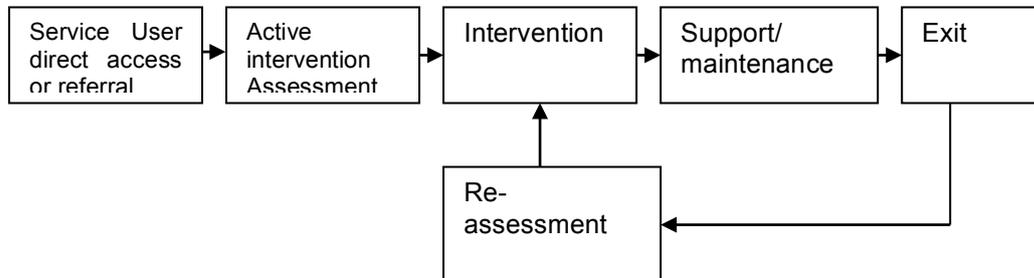
Active interventions are to be provided to Service Users for up to 12 weeks. Additional clinical support may be required for any Service User requiring assessment for prescription only medication.

#### **Definitions**

**Active Intervention Advisor** means the trained advisors appointed by the Provider to provide the Services in accordance with this Contract.

**Service** means the availability of stop smoking active intervention by the Provider appointed by the Council.

## Service Description/Care Pathway



### Service User Access

- Service Users may approach the Provider to utilise the Services direct at point of delivery i.e. at a local pharmacy, GP practice, community providers etc.
- The Services are to be provided on a one to one basis or access to group support, at the discretion of the Provider. (The chosen intervention is to be recorded by the Provider for reference at contract monitoring meetings and/or audit.) Additional training for stop smoking group work endorsed by the Council can be requested by the Provider.
- The Provider must ensure that dedicated time is available for Active Intervention Advisors to deliver the Service, including the availability of specific appointments times and appropriate private consultation space for Service Users.
- If a Service User cannot be offered an initial contact within 48 hours and an appointment within 3 days then they must be referred by the Provider to another active intervention service provider through the Gateshead Council Public Health team.
- The Active Intervention Advisor is required to facilitate Service User access to individualised support to stop smoking medicines and aids for a maximum of 12 weeks, as detailed in the 'Guidance for people providing a Stop Smoking Service' (Appendix A)
- Some Service Users may need prescription only medication. This will be accessed via the GP with whom the Service User is registered in order to ascertain whether a person will safely benefit from prescription of stop smoking medication, other than Nicotine Replacement Therapy (NRT).

### Assessment

- Delivery of stop smoking interventions must have a clear structure and content, which is to be discussed with the Service User by the Active Intervention Advisor prior to engagement and to which Service Users must commit.
- The Provider must inform Service Users of available treatment options and support (as defined by NICE Guidance) prior to commencing a quit attempt. Service Users must also be made aware that some pharmacological interventions may not be clinically appropriate for all individuals.
- The Provider will submit data on the online database for all Service Users and the Quit status must be recorded for both 4 and 12 weeks (quit, not quit, lost to follow up). If this information is not supplied by the Provider then a payment (in accordance with Schedule 3) will not be generated by the Council. In all cases, the Provider must get consent from the Service User to record and share information in accordance with information governance guidelines (see Clause 17 Service User Health Records of the Terms and Conditions of the Contract).

### **Intervention**

- The Provider must offer stop smoking interventions within professional practice accountability, to Service Users who are motivated to stop or reduce smoking.
- The Provider must ensure treatment options that are delivered comply with NICE and NCSCT guidance and current local 'Guidance for people providing a Stop Smoking Service' (Appendix A)
- The Active Intervention Advisor will deliver stop smoking services using evidence-based interventions as appropriate for the individual Service User. These could include:
  - 1:1 support, group support (open and closed) telephone and online support
  - New, non-evidence-based delivery models, which may be piloted on a small scale if agreed by the Council in advance. These must be carefully evaluated and evidence of such evaluation submitted to the Council before being adopted as a significant contributor to overall service delivery
- The Provider must facilitate access to, and where appropriate, supply stop smoking drugs and aids based on 'Guidance for people providing a Stop Smoking Service' (Appendix A). The Provider must complete all necessary paperwork to gain extra support and access to stop smoking medication for the Service User.
- The Provider and its Active Intervention Advisor must inform the Service User's GP of any stop smoking drugs supplied and of the outcome of the quit attempt.

- Interventions must be efficiently managed and there must be sufficient administrative support for general organisation, Service User contact processes and data handling to ensure all information is submitted in a timely manner.

### **Supporting a Quit Attempt**

To ensure continued monitoring, Service User compliance and ongoing access to medication:

- In weeks 1 – 4 (i.e. the 4 weeks following the quit date) the Provider must offer weekly support for a quit attempt (to ensure relapse prevention) and appointments for sessions must be scheduled when Service Users are booked into treatment.
- In weeks 4 – 12 the Provider is expected to deliver ongoing support at least once every two weeks via face to face meetings, text, phone (as appropriate)
- For individual support, a minimum of 1hr 50mins should be provided by the Provider in the period from pre-quit to 4 weeks post-quit.

Group-based intervention sessions should be at least an hour in length and offer a minimum total of six hours' contact over a six-week treatment period – i.e. pre-quit to 4 weeks post-quit.

### **Completion**

The Provider must ensure that its Active Intervention Advisors carry out a 4 and 12 week follow-up of all Service Users:

- Service Users who do not complete / drop out of the twelve week support programme must be followed up.
- Follow up must be completed in person or by telephone or text contact, with a minimum of 3 attempts by the Active Intervention Advisor to contact a Service User (where telephone contact is not feasible a letter or email must be sent). Where it has not been possible to contact a Service User after 3 attempts the Service User must be recorded as 'lost to follow-up' on the online database, follow up attempts should be documented on the Service User record.
- Smoking status is to be confirmed for all Service Users reported as having quit at 4 weeks by use of a Carbon Monoxide (CO) monitor (See Appendix B, Carbon Monoxide Monitoring Equipment), with the exception of where follow-up has been carried out by telephone. CO verification must be made in a minimum of 85% of cases.
- Adequate Service User records must be maintained by the Provider to facilitate service audits and comply with clinical governance, and kept for a minimum of 2 years. Data must be collected on all Service Users treated to support the accurate calculation of success rates. (see Clause 17 Service User Health Records of the Terms and Conditions of the Contract).

- The expected success rate of Service Users setting a quit date converting to 4 week quitters ranges from 45% to 70%.

### **Access to Medicines**

The Active Intervention Advisor must provide the Service User with access to pharmacological aids in accordance with the 'Stop Smoking Product Guide' (Appendix C). However, behavioural support should still be provided to Service Users who wish to use unlicensed, self-purchased products, whether this use is in combination with or instead of a licensed product.

In some circumstances it may be necessary to refer a Service User to their own GP (if unregistered recommend they register with a GP) e.g. for access to clinical advice.

There are 3 routes to access medication for use in the Stop Smoking Services:

1. Voucher of Recommendation (NRT Only) (**Active Intervention Advisor**). **The Provider must make this available to the Service User.**
2. Referral through recommendation for extra support and assessment of an individual's suitability (Bupropion and Varenicline) (**Clinical Intervention/GP**). **The Provider must recommend this if appropriate to the Service Users needs**
3. Prescription FP10's (NRT & Bupropion and Varenicline) (**Prescriber/GP**). **The Provider must recommend this if appropriate to the Service Users needs**

E-cigarettes are not provided by the Service.

### **General Medicines Management**

The Provider must ensure that Active Intervention Advisors:

- Only recommend pharmacological treatments that are recommended by NICE technology appraisals.
- Do not offer pharmacological treatments that have not been approved for use in Gateshead.
- Do not offer pharmacotherapy outside its product licence.
- Do not offer pharmacotherapy that is clinically inappropriate for the Service User.
- Are required to maintain a record of all pharmacotherapy e.g. by retaining a copy of the relevant Service User monitoring form or entering a record on the GP clinical system or patient medication record.
- Complete a Yellow Card if an adverse reaction is reported by a Service User. (<http://yellowcard.mhra.gov.uk>)

### **Voucher of Recommendation (NRT Only)**

- The Provider's Active Intervention Advisors who do not have a prescribing qualification, but who have undertaken the local Active Intervention Advisor training may recommend Nicotine Replacement Therapy (NRT) using the approved local NRT Voucher. NRT Vouchers must be issued in line with the local 'Guidance for people providing a Stop Smoking Service' (Appendix A).
- Eligibility Criteria for access to the NRT voucher scheme are:
  - Service Users must be motivated to stop smoking and be receiving advice by a trained Active Intervention Advisor.
  - Service Users must live or work within the borough of Gateshead.
- The NRT Voucher is to be completed by the Active Intervention Advisor indicating a recommended course of NRT for up to 12 weeks: this comprises two 1-week periods, followed by five 2-week periods. For each period of either one or two weeks, a single voucher of recommendation for NRT can be issued to the Service User.
- The advisor must record details of the recommended NRT in the Service User's records and on the online database (also see Clause 17 Service User health records of the Terms and Conditions of the Contract).
- The pharmacies participating in the local voucher scheme will provide a voucher of recommendation to the Service User.
- The Service User must be advised by the Active Intervention Advisor that the voucher is a recommendation and may be changed or declined at the point of dispensing by the pharmacist if the product is deemed to be unsuitable for the Service User.
- The Active Intervention Advisor takes full responsibility for any recommendation that they make through the voucher process.

**Referral for recommendation for extra support and assessment of Service User suitability (Bupropion and Varenicline)**

- The Provider's Active Intervention Advisors who do not have a prescribing qualification may refer to a GP for extra support and assessment of a person's suitability for stop smoking medications other than NRT (Varenicline or Bupropion) using the approved local letter of recommendation (template letter is available to the Provider from the online database)
- Active Intervention Advisors must inform Service Users that treatments recommended may not be considered clinically appropriate by their GP and may be changed or declined based on clinical judgement.
- Active Intervention Advisors recommending and prescribing pharmacotherapy must follow the 'Stop Smoking Product Guide'

(Appendix C).

### **Prescription FP10's (NRT, Bupropion or Varenicline)**

- GP prescriber or independent non-medical prescribers providing stop smoking interventions may prescribe approved stop smoking therapy on an FP10 prescription.
- The Provider's Active Intervention Advisors who are also a supplementary non-medical prescriber may supply stop smoking therapy in accordance with a clinical management plan agreed with an independent prescriber.
- The Provider's Active Intervention Advisors prescribing pharmacological therapy must ensure they maintain their professional competence.
- Prescribers must ensure they have a prescriber code and access to a suitable prescribing budget. Prescribing must adhere to local 'Stop Smoking Product Guide' (Appendix C) and other relevant local prescribing guidelines.

### **Service Promotion**

- Every contact with Service Users is also a Health Improvement contact and the Provider's Active Intervention Advisors should emphasise the benefits of stop smoking and smokefree environments, using nationally branded and listed materials.
- The Provider and the Active Intervention Advisor should promote Local and National events such as No Smoking Day and Stoptober. The promotional materials for these events will be provided through the Gateshead Council Public Health
- If the Provider also delivers NHS Health Checks they must ensure that Service Users who are identified as wanting to quit smoking during their check are offered Services under the terms of this Contract.
- Localised promotional materials will be available from the Gateshead Council Public Health for display by the Provider. This will include access to other lifestyle services available to people in Gateshead.
- The Provider must work with the Council Public Health Communications Lead service to support local marketing campaigns.

### **Response Time & Detail and Prioritisation**

The Provider must make initial contact with the Service User within 48 hours of receiving the referral (including self-referral) with an appointment offered within 3 days.

Appointments for priority groups (see section 3.1) must be made available within 2

days of referral.

### **Location(s) of Service Delivery**

The Service is to be provided within the locality of Gateshead within the opening hours of the Provider.

The Service shall be delivered from facilities and settings which are suitable for the purpose and support the confidentiality and dignity of the Service User.

### **Information Management**

Each Service User must be required by the Provider to sign a consent form to give permission to retain and share their information. The Provider must keep records of these signatures and produce them to the Council when requested for audit purposes.

In accordance with Clause 17 Service User Health Records of the Terms and Conditions of the Contract, the Provider's Active Intervention Advisor must create, maintain, store and retain Service User health records for all Service Users. The Provider must retain Service User health records for the periods of time required by Law and securely destroy them thereafter in accordance with any applicable Guidance.

The Provider and the Active Intervention Advisor must enter information onto the online database, Call it Quits, for payment by the Council and for data monitoring purposes.

### **Confidentiality**

The Provider and the Active Intervention Advisors must not disclose any confidential information unless requested by Council's authorised personnel – this includes:

- The identity of any Service User;
- The medical conditions of, or the advice received by, any Service User.
- Any information that may lead to the identification a Service User.

These are examples only and this list should not be considered exhaustive.

See Clause 13 of the Terms and Conditions of the Contract for further information.

### **Audit & Inspection**

The Provider must allow the Council's internal and other nominated auditors access to all or any papers and service records relating to this Contract for the purposes of audit and consent to the disclosure of relevant information for the purpose of fraud prevention, detection and inspection.

The Provider will be required to undertake occasional audits that are sensible, reasonable and agreed in advance between the Council and the Provider.

See Clause 34 of the Terms and Conditions of the Contract for further information.

### **3.3 Population Covered**

The Provider must make the Service available to all smokers over the age of 12 who reside or work in Gateshead in accordance with equality and diversity legislation.

The Service must accept self referrals and referrals from a range of community and health professionals, these could include midwives; hospital staff, health visitors; occupational health; pharmacists; primary care staff; community workers and others.

### **3.4 Any Acceptance and Exclusion Criteria**

The Service is only available to smokers over the age of 12. Those who have not smoked in the 48 hours prior to attending their first session are considered non-smokers: the exclusive use of nicotine vapourisers is not considered as smoking.

### **3.5 Interdependencies with Other Services**

The Provider and the Active Intervention Advisor(s) are required to work closely with Gateshead Council Public Health to ensure that Staff are appropriately trained and to support the referral pathways. Training and support are available through the Gateshead Council Public Health for all Active Intervention Providers.  
(See Schedule 1 for further information)

The Provider is responsible for ensuring the Gateshead Council Public Health are informed of the details of all Active Intervention Advisors delivering the Service on behalf of the Provider. The Provider is responsible for informing the Gateshead Council Public Health of any change in circumstances which could affect the delivery of the Stop Smoking Service.

The Provider and the Active Intervention Advisors will be required to work with Gateshead Council Public Health that support providers to be able to deliver stop smoking support. The role of the Mentor is to provide guidance to the Provider and the Active Intervention Advisor on the operational delivery of the Service including:

- Paper work
- Advertising material
- Accessing resources
- Retaining Service Users
- Use of the online database
- NRT vouchers

All Providers must comply with Performance Indicator thresholds (see Schedule 2)

### **3.6 Any Activity Planning Assumptions**

Each Active Intervention Advisor of the Provider carrying out the Services under this

Contract is expected to achieve a quit rate at 4 weeks the range of 45% to 70%.

Those Active Intervention Advisors whose rates fall below 45% will be contacted by Gateshead Council Public Health to discuss additional support. Refresher training, observed practice and coaching for Active Intervention Advisors to improve performance will be provided by Gateshead Council Public Health

The Gateshead Council Public Health will work with Active Intervention Advisors whose performance falls below 45% for a period of 3 months or more, in which circumstances the Provider will need to agree a specific Performance Improvement Action Plan should be put in place the Council. Failure to adhere to the Performance Improvement Action Plan will result in action taken under Clause 25 Termination of the Terms and Conditions of the Contract.

Active Intervention Advisors whose conversion rates are above 70% will also be approached by Gateshead Council Public Health to capture any best practice information about how to achieve these rates so that it can be shared with other providers.

## 4. Applicable Service Standards

### 4.1 Applicable national standards e.g. NICE

NICE PH1: Brief interventions and referral for smoking cessation

NICE PH5: Workplace interventions to promote smoking cessation

NICE PH6: Behavioural Change

NICE PH10: Smoking cessation services in primary care, pharmacy, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach communities

NICE PH15: Identifying and supporting people most at risk of dying prematurely

NICE PH26: Quitting smoking in pregnancy and following childbirth

NICE PH39: Smokeless tobacco cessation: South Asian Communities

NICE PH45 Tobacco Harm Reduction

NICE PH48 Smoking cessation - acute, maternity and mental health services

NICE quality standard QS43 Smoking: supporting people to stop

NICE quality standard QS82 Smoking: reducing and preventing tobacco use

The Provider and the Active Intervention Advisor are expected to maintain National Centre for Smoking Cessation and Training standards and competencies, including Local Stop Smoking Services Service and Delivery Guidance (2014)".

[http://www.ncsct.co.uk/publication\\_telephone-counselling-for-smoking-cessation-review.php](http://www.ncsct.co.uk/publication_telephone-counselling-for-smoking-cessation-review.php)

### 4.2 Applicable local standards

Not applicable

**5. Location of Provider Premises**

The Providers address as shown in the Contract Particulars.

## APPENDIX A

Guidance for people providing a 'Stop Smoking Service' on the Recommendation and Supply of 'Stop Smoking Medicines' 2014),  
[http://www.ncsct.co.uk/usr/pub/LSSS\\_service\\_delivery\\_guidance.pdf](http://www.ncsct.co.uk/usr/pub/LSSS_service_delivery_guidance.pdf)

**THIS DOCUMENT IS CURRENTLY UNDER REVIEW – UPDATED VERSION WILL BE PUBLISHED MARCH 2017**

### Overview

#### 1.1 Intended users

This guidance should be used to support the decision making process of Active Intervention Advisors (Stop Smoking Advisors) when recommending, prescribing or supplying medicines to support stop smoking attempts.

The guidance is intended to cover Gateshead, areas)

The guidance is to support the use of medicines, **not alone**, but in conjunction with an evidence based stop smoking support programme delivered by a Stop Smoking Advisor commissioned by Public Health within Gateshead Council.

The guidance therefore relates to the Stop Smoking Service and is not intended to support potential reduction in smoking or periods of abstinence.

#### 1.2 Guidance covers

Medicines only and should be used following appropriate training and in conjunction with Summary of Product Characteristics (SPCs) and Patient Information Leaflet (PILS).

It is the responsibility of the Stop Smoking Advisor to ensure that they have an appropriate knowledge of all products available so that they are able to support the client in making an informed choice about their treatment. This includes, for example, potential side effects, contraindications, cautions and drug interactions.

#### 1.3 Concerns

If the Stop Smoking Advisor has any concerns relating to the provision of medicines, or the health or wellbeing of a client, then they should be referred to an appropriate healthcare practitioner, normally the clients GP.

#### 1.4 Exclusion

The guidance is not intended to remove clinical responsibility for the recommending, prescribing and supply of medicines to support stop smoking attempts.

This guidance does not cover

- The support that is offered in conjunction with medicines
- The process of supply that is employed
- Medicines recommended, prescribed or supplied for reasons other than a stop smoking attempt

#### 1.5 Recommending - for prescription only medicines (varenicline or bupropion)

In making a recommendation to a healthcare practitioner (normally a GP or NMP) to supply a prescription only medicine (POM), it should be remembered that there is a clinical responsibility associated with writing a prescription. It should therefore **not** be assumed that this recommendation will be accepted by the person taking the responsibility for the generation of the prescription. **This should be made explicit to the client at the time of recommendation.**

## 1.6 Prescribing

The prescriber has clinical responsibility for the generation of the prescription and may choose not to generate a prescription for a client.

## 1.7 Supply

The supplier, being the pharmacist, has clinical responsibility for the supply of the medicine and retains the right not to dispense a medicine. There would normally be a reason for not dispensing a product and the reason would be made clear to the client. The reason will also be communicated to the Stop Smoking Advisor who made the request to supply. (This would normally be by phone) The potential for the pharmacist to decline to dispense should be made explicit to the client at the time of generation of a voucher or prescription unless the voucher or prescription has been generated with full access to the patient's notes and / or medical history, including concurrent medicines.

## 1.8 All practitioners should

- **Not** generate a voucher, request a prescription to be generated, prescribe or supply a medicine if they feel that the process is outside their own area of competence.
- **Not** submit to pressure from clients, or other practitioners, to generate a voucher, request a prescription to be generated, write a prescription or make supply of a medicine.
- **Ensure** that they have an appropriate level of indemnity insurance to cover them for their role within the Stop Smoking Service

## 1.9 Updates and CPD

All practitioners are responsible for ensuring that they are fully aware of the content of the SPCs and the implications of the content on their recommendations

## 2 NICE Guidance & Gateshead Council Guidance on Choice of Medicine

### 2.1 NICE (Public health Guidance 10, February 2008)

States that Stop Smoking advisers and healthcare professionals may recommend and prescribe nicotine replacement therapy (NRT), varenicline (Champix®) or bupropion (Zyban®) as an aid to help people to quit smoking, along with giving advice, encouragement and support, or referral to a Stop Smoking Service.

NICE states that one medication should not be favoured over another and that the client should be involved in the choice. However, before recommending, prescribing or supplying a treatment, the following should be taken onto account

- The person's intention and motivation to quit
- How likely it is they will follow the course of treatment
- Which treatments the individual prefers
- Whether they have attempted to stop before (and how)
- Their previous experience of stop smoking aids
- **If there are medical reasons why they should not be prescribed particular pharmacotherapy. (Medicine)**
- **Contraindications highlighted within the product licensing documentation of the pharmacological agents (medicines)**
- **The potential for adverse events associated with the pharmacological agents**
- **Potential drug interactions with other medicines, prescribed or OTC (over the counter,) that the client may be taking**

NRT, varenicline (Champix®) or bupropion (Zyban®) should be recommended, prescribed or supplied as part of an abstinence-contingent treatment, in which the smoker makes a commitment to stop smoking on or before a particular date (target stop date).

## **2.2 Combinations**

Consider offering a combination of nicotine patches and another form of NRT (such as gum, inhalator, lozenge or nasal spray) to people who

- show a high level of dependence on nicotine or
- who have found single forms of NRT inadequate in the past

However,, varenicline (Champix®) or bupropion (Zyban®) should not be offered in any combination. Further information relating to combinations can be found in Appendix 1

## **2.3 Supply**

The initial supply of medicines should only last until 1 week after the target stop date. Further recommendations, prescribing or supply should be for a maximum of 2 weeks provided that the client has demonstrated, on re-assessment, that their quit attempt is continuing.

The Stop Smoking Service supports clients for 12 weeks; this includes the facilitation of supply of medicines.

Towards the end of the 12 week period of support it may be that, in exceptional circumstances, there are clients who have maintained abstinence for almost 12 weeks but who are not yet able to cope without the support of medicines.

In these circumstances an extended period of medicines support may be requested, provided that this extension falls within the product licence of the agent being utilised by the patient.

It is considered that an extension of medicines support, for clients who have been abstinent for three months, is appropriate when weighed up against the potential for the client to recommence smoking and when the risks of smoking are weighed up against the risks, and potential benefits, of continuation of treatment.

It is usual for clients requiring support for more than 12 weeks to be referred to a healthcare professional.

In addition to this, provision of treatment beyond 12 weeks is outside the terms and conditions outlined within the Service Level Agreement. Therefore, if it is envisaged that if a client may require treatment beyond 12 weeks via the voucher scheme the commissioner of the service should be contacted in advance of the provision for authorisation to supply. **(0191 4332615)**.

**If a smoker's attempt to quit is unsuccessful further attempts may be supported.**

## **2.4 Reporting Side Effects and 'Yellow Card Scheme'**

Any side effects that the client experiences should be reported using the 'Yellow Card Scheme'. This can be done directly to the CSM (Committee on the safety of Medicines) using the yellow cards found at the back of the BNF (British National Formulary) or on line at <http://yellowcard.mhra.gov.uk/>

Advisors who are not in a position to report directly should seek advice from their line manager or the person responsible for the delivery of the stop smoking service within

their organisation (this would normally be the contractor who has signed the contract for the service or their deputy)

Clients may also report any side effects or on line at <http://yellowcard.mhra.gov.uk/>  
Further information relating to the Yellow card Scheme can be found at <http://yellowcard.mhra.gov.uk/>.

**Any risks that may be associated with NRT are substantially outweighed by the well established dangers of continued smoking.**

Users should stop smoking completely during therapy with NRT. They should be informed that if they continue to smoke while using NRT, they may experience increased adverse effects, including cardiovascular effects. (i.e. effects on the heart and circulation)

NICE has published further guidance on 'quitting smoking in pregnancy and following childbirth' (June 2010).

### **3 Useful Phone Numbers**

Commissioner of Stop Smoking Service

0191 43322615

## **Appendix B**

### **Carbon Monoxide monitoring Equipment**

All Active Intervention Advisors are allocated by the Council through the Gateshead Council Public Health an individual Carbon Monoxide monitor (CO Monitor) when they complete their basic Active Intervention training.

The Provider is responsible for the management and maintenance of all allocated equipment e.g. CO monitors which remain the property the Council.

All equipment shall be regularly cleaned, maintained and serviced as required by the Active Intervention Advisors / Provider.

CO monitors are to be calibrated by the Provider according to manufacturer's guidance to ensure accurate recording of results (usually on an annual basis).

Calibration will be carried out at Active Intervention Advisor update training sessions. Support to calibrate equipment can be obtained via Gateshead Council Public Health if required in between routine calibration dates.

### **Consumables**

Disposable mouth pieces and other consumables to support the use of CO monitors is provided free to the Provider by the Council through the Gateshead Council Public Health. For information about consumables please contact:

Gateshead Council Public Health – 0191 433 2615.

<https://sotw.callitquits.co.uk>

# APPENDIX C

## Stop Smoking Product Guide



### Stop Smoking Product Guide

Gateshead NHS Stop Smoking Service  
**0800 014 9092**  
 The National Stop Smoking Helpline  
**0800 022 4 332**

#### Treatment options

##### Varenicline (Champix) Prescription only

0.5mg/1mg (If patient experiences sickness remain at 0.5mg)

**Treatment period**  
12 weeks

##### Dependency (Fagerström score)

Titration is required to optimal dose  
 Days 103 0.5mg once daily  
 Days 407 0.5mg twice daily  
 Weeks 2012 1mg twice daily  
 (Set quit day between day 8 and 14).

The dose can be reduced to 500 micrograms (0.5mg) twice daily in those who do not tolerate the 1mg dose. Another twelve weeks of treatment can be given to abstinent individuals to reduce the risk of relapse, at the discretion of the GP.

**Advantages**  
Blocks the nicotine receptor, reducing cravings and pleasure from smoking.

**Disadvantages**  
Should be used with care in patients with history of a depression. Can cause sickness and drowsiness and dizziness. No licence for under 18 yrs. Not for use in pregnancy, breastfeeding or renal failure. Cautioned with epilepsy. Close monitoring of patients is recommended (particularly those on anti psychotic medication).

**Available Products**  
0.5, 1mg

##### Zyban (Bupropion) Prescription only

150mg tablet

**Treatment period**  
709 weeks

##### Dependency (Fagerström score)

One 150mg tablet to be taken for the first 6 days, followed by 2 tablets per day for the following 6 to 8 weeks (with at least 8 hours between each tablet).  
 A quit date should be set for between day 11 and 14.

**Note:** Patient can drop to one tablet per day if they are experiencing side effects.

**Advantages**  
Has proven to be an effective medication, with long term abstinence rates doubled compared to placebo.

**Disadvantages**  
Many possible contraindications and side effects including, drowsiness, dry mouth, insomnia and headaches. Not to be prescribed for use in pregnancy or breast feeding, under 18's, history of liver disease, kidney disease, eating disorders, head injury, seizure risk, bipolar, diabetes and depression.

**Available Products**  
150mg tablets

#### Assess nicotine dependence using Fagerström Score

##### Fagerström test for smoking dependency

		SCORE
How soon after waking up do you smoke your first cigarette?	a) Within 5 minutes	3
	b) 6-30 minutes	2
	c) 31-60 minutes	1
	d) After 60 minutes	0
Do you find it difficult not to smoke in places where smoking is not allowed (e.g., hospital, cinema, train)?	a) Yes	1
	b) No	0
Which cigarette would you find hardest to give up?	a) The first one in the morning	1
	b) Any other	0
How many cigarettes do you smoke in a typical day?	a) 31 or more	3
	b) 21-30	2
	c) 11-20	1
	d) 10 or less	0
Do you smoke more frequently during the few hours after waking than the rest of the day?	a) Yes	1
	b) No	0
Do you smoke if you are so ill that you are in bed most of the day?	a) Yes	1
	b) No	0

SCORE	
0-2	Very low dependence
3-4	Low dependence
5	Medium dependence
6-7	High dependence
8-10	Very high dependence

When using two NRT products the first should be a patch. Amounts of NRT used should be reduced over the 12 week programme (consult table).

# Treatment Options

Table illustrating NRT vs dependency

Treatment option	NRT PATCH for single use or as first product when used as dual therapy	NRT Lozenge & NRT Mini lozenge	NRT Inhalator for single use	NRT Inhalator when used as a second product (max dose 15 cartridges per day)	NRT Microtab for single use (max dose 40 pieces per day)	NRT Microtab when used as a second product (max dose 40 pieces per day)	NRT Nasal Spray for single use (max dose 64 sprays per day)	NRT Nasal Spray when used as a second product (max dose 64 sprays per day)	NRT QuickMist for single use (max dose 64 sprays per day)	NRT QuickMist when used as a second product (max dose 64 sprays per day)	NRT Gum for single use (max dose of 15 pieces per day)	NRT Gum when used as a second product (max dose of 15 pieces per day)	NRT STRIP 2.5mg for single use (max dose 15 strips per day)	NRT STRIP 2.5mg when used as a second product (max dose 15 strips per day)
<b>NRT Available</b>	25/5/10mg, 16-hour patch 21H/7mg, 24-hour patch	4mg/2mg/1mg (Lozenge) 4mg/1.5mg (MiniLozenge)	15mg	15mg	2mg	Nicotine 10mg mitred spray	Nicotine 10mg mitred spray	13.2ml spray	13.2ml spray	4mg/2mg/1mg	4mg/2mg/1mg	2.5mg oral film	2.5mg oral film	
<b>Dependency (If any) (score)</b>	Weeks 10-4 Very high / high 2.5mg/2.5mg 1 per day Medium 2.5mg/2.5mg 1 per day 15mg/4mg 1 per day	Weeks 10-4 Very high / high 4mg/8012 pieces Medium 2mg/1.5mg 8012 pieces 2mg/1.5mg 8012 pieces	Weeks 10-4 Very high / high Not suitable Medium 306 cartridges per day	Weeks 10-4 Very high / high 405 cartridges per day Medium 284 cartridges per day 183 cartridges per day	Weeks 10-4 Very high / high 2030 pieces per day Medium 1923 pieces per day 500 pieces per day	Weeks 10-4 Very high / high 5020 doses (10040 sprays) Medium 1030 doses (20600 sprays) Low/very low	Weeks 10-4 Very high / high 2032 doses (4064 sprays) per day Medium 1030 doses (20600 sprays) per day Low/very low	Weeks 10-4 Very high / high 5020 doses (10040 sprays) per day Medium 210 doses (4220 sprays) per day Low/very low	Weeks 10-4 Very high / high 5020 doses (10040 sprays) per day Medium 210 doses (4220 sprays) per day Low/very low	Weeks 10-4 Very high / high 4mg/8012 pieces Medium 2mg/8012 pieces 2mg/488 pieces	Weeks 10-4 Very high / high 4mg/8012 pieces Medium 2mg/8012 pieces 2mg/488 pieces	Weeks 10-4 Very high / high 9015 strips Medium 300 pieces 300 pieces	Weeks 10-4 Very high / high 9015 strips Medium 300 pieces 300 pieces	
<b>Please note: ALL DOSES SHOWN ARE PER DAY</b>														
<b>TREATMENT PERIOD</b>	Weeks 5-8 Very high / high 4mg/1mg 1 per day Medium 15mg/4mg 1 per day Low/very low 10mg/7mg 1 per day	Weeks 5-8 Very high / high 4mg/8012 pieces Medium 4mg/8012 pieces 2mg/1.5mg 488 pieces 2mg/1.5mg 104 pieces	Weeks 5-8 Very high / high Not suitable Medium 305 cartridges per day 204 cartridges per day	Weeks 5-8 Very high / high 283 cartridges per day Low/very low 182 cartridges per day	Weeks 5-8 Very high / high 5015 pieces per day Medium 5015 pieces per day 307 pieces per day	Weeks 5-8 Very high / high 3020 doses (6040 sprays) per day Medium 5010 doses (10020 sprays) per day Low/very low	Weeks 5-8 Very high / high 3020 doses (6040 sprays) per day Medium 5010 doses (10020 sprays) per day Low/very low	Weeks 5-8 Very high / high 3015 doses (6030 sprays) per day Medium 210 doses (4200 sprays) per day Low/very low	Weeks 5-8 Very high / high 3015 doses (6030 sprays) per day Medium 210 doses (4200 sprays) per day Low/very low	Weeks 5-8 Very high / high 4mg/485 pieces Medium 2mg/488 pieces 2 mg/105 pieces	Weeks 5-8 Very high / high 4mg/485 pieces Medium 2mg/488 pieces 2 mg/105 pieces	Weeks 5-8 Very high / high 485 pieces Medium 385 pieces 385 pieces	Weeks 5-8 Very high / high 485 pieces Medium 385 pieces 385 pieces	
<b>Advantages</b>	Easy to use with excellent safety and tolerability profile.	Minis more discreet than the standard lozenge. Fast acting.	Helps to keep hands/ mouth busy.	Helps to keep hands/ mouth busy.	Can be used discretely; easy to adjust dose; very few side effects.	Can be used discretely; easy to adjust dose; very few side effects.	Works quickly and easy dose adjustment.	Works quickly and easy dose adjustment.	Works quickly and easy dose adjustment.	Helps to keep hands/ mouth busy.	Helps to keep hands/ mouth busy.	Works and dissolves quickly.	Works and dissolves quickly.	
<b>Disadvantages</b>	Localised itching/ discomfort may occur at first but should fade. 24-hour patches may cause sleep disturbance.	Stomach upset; stinging in mouth; hiccup; localised irritation. Large lozenge/ high sodium content, bulky.	Most effective if used with shallow puffing action. Not to be inhaled into the lungs.	Most effective if used with shallow puffing action. Not to be inhaled into the lungs.	Stomach upset; stinging in mouth; hiccup; localised irritation.	Stomach upset; stinging in mouth; hiccup; localised irritation.	May cause sneezing and irritation at first; runny nose, watering eyes.	May cause sneezing and irritation at first; runny nose, watering eyes.	Hiccups; stinging mouth; localised irritation.	Difficult with dentures, jaw ache, stomach upset, hiccup; localised irritation.	Difficult with dentures, jaw ache, stomach upset, hiccup; localised irritation.	Smokers with a recent heart attack, stroke, unstable or worsening angina, blood pressure or any medical condition should only use under medical supervision.	Smokers with a recent heart attack, stroke, unstable or worsening angina, blood pressure or any medical condition should only use under medical supervision.	
<b>Available Products</b>	NRT 16-hour patch: 15mg/4mg/2mg/7Z NRT 24-hour patch: 15mg/4mg/2mg/7Z	Lozenge 4mg/2mg/1.5mg pack of 96/72 mini lozenge 4mg/1.5mg pack of 60	Pack of 4, 20, 36	Pack of 4, 20, 36	2mg Microtab pack of 30, 100	2mg Microtab pack of 30, 100	10mg Nasal Spray pack of 96, 24	10mg Nasal Spray pack of 96, 24	13.2ml spray, 2 x 13.2ml spray	13.2ml spray, 2 x 13.2ml spray	Nicorette 105, 30 Nicotinon CD, 96, 24 Nicotinal, 96, 24	Nicorette 105, 30 Nicotinon CD, 96, 24 Nicotinal, 96, 24	2.5mg oral film Pack of 15, 60	2.5mg oral film Pack of 15, 60

## SCHEDULE 1

### CONDITIONS PRECEDENT

1. **GPhC**  
Provide the Council the General Pharmaceutical Council Registration Number for the pharmacy premises along with details of a Pharmacy Superintendent and their GPhC Number.
2. **Insurance**  
Provide the Council with a copy of the insurance policies to illustrate that the Required Insurances (as detailed in the Terms and Conditions and Invitation to Tender) are in place;
3. **Training & Qualifications**
  - Anyone wishing to provide an Active Intervention NHS Stop Smoking Service must complete the training endorsed by the Council and approved by the Gateshead Council Public Health and meet the national competencies for Stop Smoking Advisors (as set out by the National Centre for Smoking Cessation and Training ('NCSCT') <http://www.ncsct.co.uk/>).
  - All Active Intervention Advisors should have completed the NCSCT Stage One online training programme in order to access the 2 days training course. <http://www.ncsct.co.uk/>
  - In addition the Provider/ Active Intervention Advisors are required to meet update requirements, currently attendance at annual update training, or undertake other updates by the Council and be responsible for ensuring that their CO Monitor is maintained and calibrated in line with manufacturer's guidance.
  - In the circumstance that an Active Intervention Advisor has been inactive for a period of 6 months then a refresher training session be required to be undertaken before Service delivery can commence.
  - In the circumstance that an Active Intervention Advisor has been inactive for a period of one year or more they will be required to complete the full Active Intervention Advisor Training (2 days) to continue practising as an advisor.
  - Staff involved in delivery of 'rolling groups' or 'drop in clinics' must be trained to national standards and such groups must be delivered by advisors with sufficient expertise to support quitters at different stages of the quitting process simultaneously. Training to provide this support is in addition to the Active Intervention Advisor training.
4. **Patient Group Directive**  
  
Not applicable

## SCHEDULE 2

### PERFORMANCE INDICATORS

The Provider must supply the Council with such information as it may reasonably request for the purposes of monitoring the Provider's performance in relation to this Service.

#### Data Collection

Service User monitoring forms must be completed by the Provider for each quit attempt using the online database provided by the Council

(<https://sotw.callitquits.co.uk>) for each Service User who sets a quit date. All fields must be completed to ensure data is not lost.

Data returns should include details of Service Users receiving NRT, Bupropion (Zyban) or Varenicline (Champix), as appropriate.

#### Data Submission Dates

Data entered onto the database (online database) will automatically be used by the Council to generate payments at the end of each month and it is the responsibility of the Provider to ensure information is up to date for payment. Any delay in submitting data will result in a delay in payment.

NHS Stop Smoking Services are monitored nationally and regionally on a quarterly basis. The information for this submission will be taken from the database.

The following table sets out the Performance Indicator Threshold levels to be met by the Provider:

Performance Indicators	Threshold	Method of Measurement	Consequence of breach
Quit rate at 4 weeks	45-70%	Data taken from Online database	Quit rate below 45% support from mentor. Below 45% for 6 months referred to Council's commissioners to review the Contract.
Minimum number of individuals setting quit dates per annum	6	Data taken from Online database	Action under Clause 24 of the Terms and Conditions (Default and Suspension)
CO verified 4 week quit	85%	Data taken from Online database	Action under Clause 24 of the Terms and Conditions (Default and Suspension)
Quit rate at 12 weeks	To be monitored	Data taken from Online database	Action under Clause 24 of the Terms and Conditions

			(Default and Suspension)
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Data will be taken from the online database in the following areas to assess where support is required to the Provider from Gateshead Council Public Health. The Provider must ensure that data is recorded on the online database:-

- Number of individuals setting a quit date
- Number of 4 week quits
- Number of CO verified 4 week quits
- Number of 12 week quits
- Number of CO verified 12week quits
- Number of lost to follow ups

### SCHEDULE 3

#### PRICING

In consideration of the Provider delivering the Service the Council will pay the Provider the following Price

Element to be Delivered	Amount
Quit Date Set	£15.50
4 week quit	£41.00
12 week quit	£41.00

The Provider shall submit to the Council on a monthly basis all information relating to number of quit dates set, 4 week quits and 12 week quits achieved using the online database which will automatically generate a claim for each payment. It is the responsibility of the Provider to ensure that all data entered onto the online database is accurate and up to date by the end of each month. Any delay in submitting data will result in a delay in payment. The Council shall pay the Provider the price following verification of the online claims, within 30 days of the end of the month.

The Price shall remain as set out in this Schedule during the financial years 2017 and 2018.

In the event that the Contract is extended in accordance with Clause 2.4 of the Terms and Conditions the Price shall continue at the same rate, unless a variation is agreed with Council. Where appropriate, the Council shall pay the Price on a pro-rata basis in respect of any extension period.