Locala Stop Smoking Service

Service Level Agreement for Nicotine Replacement Therapy Voucher Scheme

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Stop Smoking Specialist
Introduction

NHS Kirklees have commissioned Locala Community Partnerships CIC to administer a pharmacy voucher scheme for the supply of Nicotine Replacement Therapies (NRT) across Kirklees. The administration of this scheme will be carried out by the Locala Stop Smoking Service (LSSS). The scheme enables patients using Locala’s Stop Smoking Service and the Pharmacy/Dental Stop Smoking Service to issue a voucher for NRT. This service level agreement forms the agreement between Locala Community Partnerships CIC and the pharmacy who wishes to issue vouchers/ dispense NRT under this scheme.
Summary

Smoking is the primary cause of preventable morbidity and premature death, accounting for 81,400 deaths in England in 2009 (1).

The Government is committed to reducing smoking rates (1), and smoking cessation guidelines have been published including the cost effectiveness of interventions for smoking cessation (2). These guidelines recommend that all smokers should be asked about their smoking habit at every opportunity, advised to stop smoking, offered assistance where appropriate and follow up arranged to reassess smoking status. The guidelines include the provision of nicotine replacement therapy as a pharmacological aid for smoking cessation.

Nicotine Replacement Therapy (NRT) has been shown to approximately double cessation rates compared with controls (3), and smoking cessation guidelines recommend that smokers should be encouraged to used NRT as a cessation aid.

Efficacy

Cochrane carried out a meta-analysis of 81 trials involving 25,600 smokers to examine the effectiveness of all forms of NRT, compared with placebo or no NRT (4). This study showed that all forms of NRT were significantly more effective than placebo or no NRT, in helping smokers to achieve abstinence. The pooled results for all forms of NRT showed that 18% of all patients receiving treatment were still abstinent at 52 weeks, compared with 11% in the control group.

Data on direct comparisons of the different forms of NRT with each other are limited. Overall, there is little evidence to suggest superiority of any one form of NRT (5). It is recommended that choice of product is tailored to the patient (6).

Adverse Effects

NRT products provide much lower doses of nicotine than is obtained by smoking and its adverse effects are not complicated by the additional toxic effects of tar and carbon monoxide generated by cigarette smoke.

With the use of patches there is a possibility of localised skin reaction (7). Nicotine can also exacerbate symptoms in patients with peptic ulcers or gastritis, and the possibility of this is greater with the gum than other NRT products, as nicotine may be swallowed and enter the stomach directly (7). Denture wearers may also have difficulty in chewing gum.

In addition, NRT products may produce the same range of side effects as nicotine from smoking (hiccups, sore throat, headache, nausea and dizziness). However, these side-effects are less likely to occur than with smoking, and clinical trials have shown most to be comparable to those caused by placebo (8).
**Special Precautions**

Nicotine is a known stimulant and is associated with an increased risk of angina, atherosclerosis, stroke and other cardiovascular disease.

The manufacturers advise that doctors should assess the possible risks and benefits of using NRT versus cigarettes in the following patient groups:

- History of angina
- Recent myocardial infarction
- Recent cerebrovascular accident
- Serious cardiac arrhythmias
- Pregnant and breast feeding women

These are **NOT** contra-indications and it is preferable for a patient in any of the above groups to stop smoking with the use of NRT rather than continue smoking.

Nicotine can also stimulate production of adrenaline; NRT should therefore be used with caution on patients with diabetes mellitus, hyperthyroidism or phaeochromocytoma. Again NRT presents a lesser hazard than smoking.

**Significant changes in the use of NRT with previously cautioned / contra-indicated groups (Dec 2005)**

Ref: Safety of NRT – Helping Smokers to Stop – Advice for Pharmacists in England (9)

**Adolescent smokers**

Many young smokers show signs of nicotine dependence. Although there is little published data demonstrating the efficacy of NRT in young smokers, there is no logical reason why it should not help as long as it is used correctly and the smoker is determined to give up. NRT products are now licensed for use by smokers under 18. Ultimately the decision to use NRT should be based on the smoker’s determination to quit, and on their level of dependence (as opposed to age). Given that NRT is less harmful than smoking, safety concerns should not be a barrier to use.

**Cardiovascular disease**

Although nicotine has some acute effects on the cardiovascular system, unlike tobacco smoke it is not a significant risk factor for cardiovascular disease or acute cardiac events. Nicotine replacement therapy provides less nicotine, less rapidly than cigarette smoking, without substances such as carbon monoxide (which is known to have adverse effects on the cardiovascular system). On this basis, experts agree that all NRT products can be safely used by smokers with stable cardiovascular disease. It is recommended that the risks and benefits of using NRT should be assessed for smokers with unstable cardiovascular disease, or
who have suffered an acute event in the past four weeks. If the only other option for this group is continued smoking, a risk–benefit assessment invariably leads to recommending NRT. When using NRT for smokers with unstable cardiovascular disease, it is advisable to use the shorter-acting oral products that can be discontinued immediately in the event of any problems. Nicotine patches, even once removed, leave a small reservoir of nicotine under the skin.

**Pregnant and breastfeeding women**

Smoking during pregnancy is associated with large risks to both mother and foetus, and later to the newborn and growing infant. Although nicotine may be implicated in some of the adverse effects of smoking (e.g. low birth weight and behavioural problems in infants), NRT delivers much less nicotine than cigarettes without the other harmful ingredients of tobacco smoke. It is better for pregnant women to be both nicotine- and tobacco-free. Whilst there is not sufficient evidence at present on the effect of NRT on cessation in pregnant women, the overwhelming evidence for effectiveness generally and the need to stop smoking to protect the baby mean that NRT should be offered to pregnant smokers who have not given up and who feel that they would be unable to give up without it.\(^{10}\)

When considering NRT use, it is prudent to document any discussion of risks and benefits, and oral products should be recommended initially as these will provide less nicotine to the foetus than a patch. If oral products are not acceptable a patch may be considered, but this must be removed before going to bed, i.e. the patch should not be used for more than a 16-hour period, with a break of 8 hours between patches. Treatment should be provided as early in pregnancy as possible, with the aim of being smoke-free and nicotine-free by the third trimester.

The use of NRT while breastfeeding, is associated with very few risks to the child. Nicotine does accumulate in breast milk but relatively little is absorbed from the infant’s gut, and this then undergoes first pass metabolism resulting in a low plasma concentration. Any small risk to the child from this low level of nicotine is preferable to the risk of the breastfeeding woman continuing to smoke.

Smoking can cause great harm to the mother, the unborn child and the newborn infant, and would-be parents should be advised of these risks. Treating pregnant smokers involves specific challenges (e.g. the immediacy of the need to stop; the mother’s fear of being judged), and clients may be best supported by a specialist smoking and pregnancy advisory service, where this exists. Pharmacists will need to discuss local treatment options carefully with pregnant women and help them decide which service is likely to be the most appropriate for their needs.

The following table indicates specific actions to be followed for patients with a variety of underlying conditions that may impact on their use of NRT products.
Guidance summarised from Report on Safety of Medicines Working Group on Nicotine Replacement Therapy
Medicines and Healthcare products Regulatory Agency / Committee on Safety of Medicine (Dec 2005)

<table>
<thead>
<tr>
<th>Question</th>
<th>Action if yes</th>
<th>Suggested product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the voucher holder aged between 12 and 18?</td>
<td>• Confirm the client is being supported by a trained smoking cessation advisor</td>
<td>• Any product suitable</td>
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<tr>
<td></td>
<td>• Dispense product if no contraindications</td>
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</tr>
<tr>
<td>Is the voucher holder pregnant or breast-feeding?</td>
<td>• Confirm the client has already received at least 1 prescription during this quit attempt from</td>
<td>• Intermittent dosing products may be preferable as these usually provide a lower daily dose of nicotine than patches. Slow release 24-hour patches should not be used to avoid the administration and exposure of the foetus to nicotine overnight. However, if the woman suffers from nausea and/or vomiting, a 16-hour patch removed at night is preferable. • For breast feeding mothers, intermittent NRT products will allow the time between NRT use and feeding to be as long as possible.</td>
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<tr>
<td></td>
<td>their GP. If not refer client to GP for first prescription using letter provided. Contact advisor who issued voucher as soon as possible to inform them that a referral has been made. • Is client already using one NRT product? Refer to GP for prescription for any additional product.</td>
<td></td>
</tr>
<tr>
<td>Has the voucher holder been hospitalised with a recent myocardial infarct, severe dysrhythmia or cerebrovascular accident within the last 4 weeks and/or are they considered to be haemodynamically unstable?</td>
<td>• Refer patients to their GP / Consultant using letter provided. Contact advisor who issued voucher to inform them that a referral has been made</td>
<td>• This group should be encouraged to stop smoking with non-pharmacological interventions • With GP or Consultant approval any product could be dispensed</td>
</tr>
<tr>
<td>Does the voucher holder suffer from lung disease? E.g. Asthma / COPD / chronic throat disease</td>
<td>• Consideration of appropriate product</td>
<td>• Patients with obstructive lung disease may find use of the inhalator difficult. Nicotine</td>
</tr>
<tr>
<td>Question</td>
<td>Instructions</td>
<td>NRT Products</td>
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<td>-------------------------------------------------------------------------</td>
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<tr>
<td>Does the voucher holder suffer from diabetes mellitus?</td>
<td>Advise client they may need to monitor blood glucose levels more closely as catecholamines released by nicotine can affect carbohydrate metabolism</td>
<td>Any product suitable</td>
</tr>
<tr>
<td>Does the voucher holder suffer from moderate to severe hepatic impairment and/or severe renal impairment?</td>
<td>Use with caution with this group as the clearance of nicotine or its metabolites may be decreased with the potential for increased side effects.</td>
<td>Any product suitable</td>
</tr>
<tr>
<td>Is the voucher holder taking drugs metabolised by CYP 1A2 / CYP 1A1 e.g. theophylline, clozapine and ropinirole?</td>
<td>Advise patient to inform their consultant they have stopped smoking. Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possible CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window e.g. theophylline, clozapine and ropinirole</td>
<td>Any product suitable</td>
</tr>
<tr>
<td>Does the voucher holder suffer from GI disease?</td>
<td>Advise client swallowed nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastritis or peptic ulcers and oral NRT preparations should be used with caution in these cases.</td>
<td>Patch (24 and 16 hr)</td>
</tr>
<tr>
<td>Does the voucher holder suffer from any generalised dermatological disorders?</td>
<td>Patients with chronic generalised dermatological disorders such as psoriasis, chronic dermatitis or urticaria should not use NRT patch.</td>
<td>Nicotine gum, nasal spray, lozenge or sublingual tablet, inhalator,</td>
</tr>
<tr>
<td>Does the voucher holder suffer from phaeochromocytoma and / or uncontrolled hyperthyroidism?</td>
<td>As nicotine causes the release of catecholamines, NRT should be used with caution in patients with phaeochromocytoma and / or uncontrolled hyperthyroidism.</td>
<td>Any product suitable</td>
</tr>
</tbody>
</table>
Interaction with other medicinal products

No clinically relevant interactions between NRT and other drugs have definitely been established. However nicotine may possibly enhance the haemodynamic effects of adenosine i.e. increase in blood pressure and heart rate and also increase pain response (angina-pectoris type chest pain) provoked by adenosine administration.

Protocol for providing Nicotine Replacement Therapy via the Voucher Scheme:

Nicotine Replacement Therapy Vouchers pads will be given to all Smoking cessation Specialist advisors and Intermediate advisors who are based in Pharmacies and Dental Practices

Voucher pads are to be kept in accordance with the Good practice guidelines for the safe and secure handling of voucher pads. (Appendix 1)

- To issue NRT vouchers you must be:
  - A Specialist Advisor working for LSSS OR
  - An Intermediate Advisor accredited by LSSS and working in a pharmacy or dental practice in Kirklees
  - Have attended the voucher scheme training
  - Have signed up and received a voucher pad

- Only clients who are attending LSSS or a Smoking Cessation clinic in a pharmacy/dental practice participating in the smoking cessation Local Enhanced Scheme (LES) will be eligible to be issued with a voucher

- All clients will be screened to assess nicotine dependence, motivation and readiness to stop smoking by the Specialist/Intermediate Stop Smoking Advisor.

- Prior to their quit day, as part of the cessation planning and preparation process, the client will initially receive a voucher for 2 weeks supply of NRT to commence use on the day they stop smoking. (Vouchers will be valid for 4 weeks from the issue date)

- In those cases where the client smokes more than 20 cigarettes a day or equivalent tobacco, dual therapy may be offered.

- At one week after ‘quit day’, the client will be issued with a voucher for a further 2 weeks supply of NRT.

- 3 weeks following the client’s ‘quit’ day, the client will be assessed for abstinence from smoking using carbon monoxide verification by the Specialist/pharmacy/dental advisor.

- If there is evidence the client is still smoking, no further NRT vouchers will be issued.

- Should the client’s abstinence be verified, vouchers for a further 4 week supply of NRT will be given.

- If the client is still not smoking 4 weeks after their quit date and choose not to have further support after that time, or have attended a group that ceases at that time, they may receive a voucher asking for the rest of the NRT course to be supplied (this could be up to 4 weeks supply of NRT)
In total this means there will be 4 vouchers (if the client finishes the full course of medication) and will follow a 2 weeks, 2 weeks, 4 weeks and 4 weeks course of medication.

All vouchers will be marked with status of supply e.g. Voucher 1, voucher 2 etc.

Dispensing details

NRT vouchers will be redeemable at any pharmacy which has signed up to dispense via the Voucher Scheme.

All clients will be screened to assess nicotine dependence, motivation and readiness to stop smoking by the Specialist Stop Smoking Advisor or the pharmacy/Dental advisor. The patients’ suitability to receive NRT will be assessed by the contracted pharmacist, using the guidelines provided by Locala Stop Smoking Service (table on pages 6 and 7 of this document).

Should a client fall into a patient group with special warnings/ precautions, where a second opinion should be sought, (pregnancy/breastfeeding or hospitalisation in the last 4 weeks through a cardiovascular/cerebrovascular event) a prescription will be required from the patient’s GP or Consultant before NRT may be issued. The advisor must request the first 2 weeks of medication from the GP/Consultant in the first instance, if no cautions identified then NRT vouchers can be given for follow up treatment. If a voucher has been issued and the pharmacy assessment identifies that the client falls into the special warnings/precautions group; they must notify the advisor as soon as possible. In these cases the voucher should be retained, marked as Void and returned with the monthly summary sheet.

Following the initial clinical assessment, it is the responsibility of the dispensing pharmacist to check there have been no changes in the client’s medical status. Should a client present a voucher for continued treatment to a pharmacist who did not conduct the initial assessment, a new assessment should be completed.

Should the initial NRT product be unsuitable for the client, the client should go back to the advisor who will re-assess and issue a further voucher for an alternative product. To minimise the chance of fraud it is advisable that when NRT is supplied under this scheme the barcode be marked and in those cases where the NRT product is unsuitable, unused NRT products are to be returned to the pharmacy and destroyed in line with Medicines Management Policy – A Guide to the Safe and Secure Handling of Medicines(11). In these cases the service will reimburse the pharmacy in the normal way; however we envisage a maximum of 1 change of NRT per quit attempt.
Client Payment details

- If the client pays for prescriptions a fee equal to that of the normal prescription charge should be collected per item dispensed.
- If the client receives free prescriptions, they should complete the exemption and declaration on the back of the voucher.
- It is the pharmacist’s responsibility to request evidence of exemption from prescription charges and the pharmacist should confirm on the back of the voucher whether evidence of exemption has been seen.
- Clients who hold pre-payment certificates will be exempt from the prescription fee.

Reimbursement

- The pharmacist should send the completed bottom yellow copy of the voucher (with the exemption declaration) to Locala Stop Smoking Service, Dewsbury Health Centre, Wellington Road, Dewsbury, WF13 1NH, to reach them by the 5th of the following month. Any forms received outside of this period will result in a delay for the reimbursement to the following month.
- The pharmacist should retain the pink copy of the voucher for their own records.
- The copies must be stored safely for 2 years and thereafter shred confidentially.

Fees

- Locala Stop Smoking Service (LSSS) will pay the pharmacists £3.00 per item on the voucher.
- LSSS will reimburse the pharmacist the cost of the product (Drug Tariff plus VAT @ reduced rate - 5%) on a monthly basis.

Additional Pharmacist Duties

The participating pharmacy and ultimately the person stated in the service agreement have a duty to:

- Produce a Standard Operating Procedure for the service that corresponds to the procedures and documentation provided by LCP. The standard operating procedure should include error and near miss reporting.
- Ensure the service is underpinned by a system of clinical governance, which ensures that the service is of a high quality, provided to the agreed standard and supports pharmacists to deliver patient care.
- Ensure that pharmacists and staff involved in the provision of the service have the relevant knowledge and competencies and are appropriately trained in the operation of the service.
- Ensure that any locum providing the service has the appropriate knowledge and is competent to operate the service.
Ensure that pharmacists and staff involved in the provision of the service are aware of and operate within local protocols.

Ensure that the LSSS Manager is promptly informed of any change in pharmacy personnel/ circumstances that mean that either more pharmacists need training or the pharmacy is unable to participate in the service.

Pharmacists are reminded that they are to be vigilant to the possible fraudulent use of the service by patients or other pharmacists. If this is suspected the LSSS Manager is to be contacted.

Ensure that the pharmacy maintains appropriate records to ensure effective ongoing service delivery and audit.

Allow an authorised agent of the Locala Community Partnership (LCP) access to all documentation for audit/fraud purposes, at any reasonable time.

Ensure that pharmacy has the appropriate professional indemnity insurance.

Ensure the pharmacy participates in any quality indicator assessments as requested by the LCP.

Core Competencies for Pharmacists

All pharmacists involved in Pharmacy Voucher Scheme have a professional responsibility to develop, reinforce and update their knowledge and skills. Further information can be found at:

http://www.ncsct.co.uk/Content/FileManager/documents/NCSCT_Training_Standard.pdf

Locala Stop Smoking service offer Brief Interventions training in Smoking Cessation throughout the year. For more information and to book a place visit:

http://publichealthtraining.kirklees.nhs.uk

Confidentiality

All parties agree that access to records and documents containing information relating to individual clients treated under the terms of this Voucher Scheme SLA will be restricted to authorised personnel. The pharmacy will comply with the Data Protection Act, Caldicott and other legislation covering access to confidential client information.

Indemnity

The pharmacist will ensure that they hold appropriate clinical indemnity against any claim from a client arising from the provision of this service. Evidence will be provided annually to LCP.
Incidents and Near Misses

Incidents and near misses should be reported directly to the LCP using a Serious Untoward Incident Reporting Form (SUI), available from LCP CIC. Incidents relating to the Pharmacy Voucher Scheme must be sent directly to LCP even if this is not the pharmacies usual route for incident reporting.

Complaints

The pharmacist will effectively manage any complaints or incidents using the pharmacies own complaints procedure, keeping a record for audit purposes. If the complainant is not happy with your response or does not wish to discuss the complaint with the pharmacy they should contact:

Customer Liaison Manager,
Locala Community Partnerships
First floor, Beckside Court,
Batley
West Yorkshire
WF17 5PW
Email: enquiry@locala-cic.nhs.uk
Telephone: 01924 351531

LCP duties

LCP will agree with local stakeholders the Nicotine Replacement Therapy formulary for this service. They will regularly review the formulary to ensure that the formulary reflects the availability of new medicines and changes in practice or guidelines, as well as relevant NICE guidelines.

LCP will pay the pharmacy operating the scheme as outlined in Fees.

LCP will provide a framework for the recording of relevant service information for the purposes of audit and the claiming of payment.

LCP will provide details of relevant referral points which pharmacy staff can use to signpost service users who require further assistance.

LCP will supply patient information leaflets for use in the service.

LCP is responsible for the promotion of the service locally, including the development of publicity materials, which pharmacies can use to promote the service to the public.
Quality Indicators

- The pharmacy has appropriately provided patient information leaflets and provides these as per the service specifications.
- The pharmacy reviews its standard operating procedures and the referral pathways for the service on an annual basis.
- The pharmacy co-operates with any locally agreed PCT-led assessment of service user experience.

Monitoring arrangements

The PCT will monitor the service delivery as part of the pharmacy contract monitoring process to ensure consistency of high quality service delivery. Potentially, any element of the services provided may be monitored. The elements to be monitored will be shared with the contractors before any monitoring visit. Elements likely to be monitored are the existence of a SOP, with a review date, signed and dated by relevant staff and availability of patient information leaflets.

Duration of Agreement

This agreement shall commence on the date the authorisation is signed by both parties and shall continue until further notice. This service will be reviewed quarterly and evaluated yearly. At least 28 days notice must be given by either party to terminate or change Voucher Scheme SLA. LCP retains the right to withdraw the scheme at any time if it is deemed to be unsuccessful or if the Voucher Scheme SLA is seriously breached.
References


2. Stop smoking service delivery and monitoring guidance 2011/12 (2011)

3. Smoking Cessation Guidelines and their Cost Effectiveness Thorax (Dec 1998); 53: S1-S38


6. Nicotine replacement therapy. MeReC 1999; 10, (3) 9-12


Locala Community Partnerships CIC.

Pharmacy Voucher Scheme to Supply Nicotine Replacement Therapy to Patients of the Locala Stop Smoking Service and, Pharmacies/Dentists operating under the Local Enhanced Service

Issued: November 2011
Date of Review: November 2012
Drawn up by: Amina Hans-Adam

This Access Scheme has been approved by:

<table>
<thead>
<tr>
<th>Title</th>
<th>Name</th>
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<tbody>
<tr>
<td>Tobacco Programme Manager/Commissioner</td>
<td>Kirsten Foster</td>
</tr>
<tr>
<td>Locala Stop Smoking Service</td>
<td>Sandra Hall</td>
</tr>
<tr>
<td>Head of Medicines Management LCP</td>
<td>Lucianne Ricketts</td>
</tr>
</tbody>
</table>

Clinical Condition or Situation to which the Pharmacy Voucher Scheme Applies:

<table>
<thead>
<tr>
<th>Define situation/condition</th>
<th>Adjunct to smoking cessation therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objectives of care</td>
<td>To reduce nicotine withdrawal symptoms on cessation of smoking</td>
</tr>
</tbody>
</table>
| Criteria for inclusion     | • Clients attending Locala Specialist Stop Smoking Service, pharmacy or dental practice requiring smoking cessation support by IA’s and wanting to use nicotine replacement therapy.  
• Clients who have been assessed for nicotine dependence, motivation and readiness to stop smoking by a specialist stop smoking advisor Or IA in Pharmacy or dental practice  
• Clients attending Kirklees pharmacies or dentists operating under the Smoking cessation LES |

Action if special precautions/warnings with | Refer to MHRA/CSM Guidance in tables on pages 6 and 7.
NRT

Pregnant/breastfeeding women to be referred to GP/Consultant for first supply of nicotine replacement therapy or for addition of a second NRT product. Patients hospitalised within the last 4 weeks due to cardiovascular/cerebrovascular disease i.e. Myocardial infarction, severe dysrhythmia, cerebrovascular accident or those considered haemodynamically unstable to be referred to GP/Consultant for first supply of nicotine replacement therapy.

| Action if patient declines treatment | Not Applicable |

**Characteristics of Stop Smoking Advisor within pharmacy or dental setting/Specialist:**

<table>
<thead>
<tr>
<th>Registration required</th>
<th>Registered with Locala Stop Smoking Service</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continued training requirements</td>
<td>Annual update</td>
</tr>
</tbody>
</table>

**Characteristics of Listed Pharmacist:**

<table>
<thead>
<tr>
<th>Qualifications required</th>
<th>Registered pharmacist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional experience / training required</td>
<td>Attended pharmacy voucher scheme workshop / or induction meeting with representative of LSSS</td>
</tr>
</tbody>
</table>

**Management and monitoring of Voucher Scheme:**

- The Access Scheme is to be read, agreed to and signed by all Registered Stop Smoking Advisors and pharmacists it applies to.
- One signed copy will be given to each Pharmacy with a scanned copy of the original being kept on file by LCP. Details of all patients who have been issued with NRT under the voucher scheme will be recorded for audit purposes within LCP confidentiality procedures.
Locala Stop Smoking Service

Nicotine Replacement Therapy (NRT) Pharmacy Access Scheme

Applies to the use of Nicotine Replacement Therapy products, including specific groups as listed under special warning/precautions provided through the Locala Pharmacy Voucher Scheme. See pages 3 to 7 for more detailed guidance.

Sandra Hall
Locala Community Partnerships
Service Manager

Amina Hans-Adam
Locala Community Partnerships
Stop Smoking Specialist Advisor
<table>
<thead>
<tr>
<th>Drug</th>
<th>Special warnings/Precautions</th>
<th>Formulation and Route of Administration</th>
<th>Dose and Frequency</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gum</td>
<td>Nicotine bound to an ion exchange resin</td>
<td>Chewing releases nicotine which is absorbed through the mouth</td>
<td>4mg as required – up to a maximum of 15 pieces daily (individual manufacturers may vary) Avoid acidic beverages, coffee and soft drinks 15 minutes before use</td>
<td>Continue using as required for 8-12 weeks then gradually reduce gum use over the next 4 weeks. When daily use is 1-2 pieces, gum should be stopped.</td>
</tr>
<tr>
<td>Nicotine replacement gum containing 4mg nicotine</td>
<td>• Cardiovascular disease • GI Disease (incl Peptic ulcer) • Diabetes Mellitus • Renal or hepatic impairment • Phaeochromocytoma and uncontrolled hyperthyroidism • Pregnant/breastfeeding (avoid liquorice flavoured gum during pregnancy) * • Those taking medication which may require dose adjustment</td>
<td></td>
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<tr>
<td>Nicotine replacement gum containing 2mg nicotine</td>
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<tr>
<td>Inhalator</td>
<td>Mouthpiece containing a plug impregnated with nicotine</td>
<td>Provides nicotine via oral inhalation. Nicotine is absorbed mainly via the buccal mucosa.</td>
<td>Puff on the inhalator as required when experiencing the urge to smoke. Replace cartridge after 20 minutes of use.</td>
<td>12 weeks broken down as below</td>
</tr>
<tr>
<td>Inhalator containing 10mg nicotine per cartridge</td>
<td>• Cardiovascular disease • GI Disease (incl Peptic ulcer) • Diabetes Mellitus • Renal or hepatic impairment • Phaeochromocytoma and uncontrolled hyperthyroidism • Chronic throat disease and bronchospastic disease • Pregnant/breastfeeding women * • Those taking medication which may require dose adjustment</td>
<td></td>
<td>6-12 cartridges per day 8 weeks</td>
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<td></td>
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<td>Reduce number of cartridges used by half 2 weeks</td>
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<td></td>
<td></td>
<td>Reduce gradually to zero by last day 2 weeks</td>
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<tr>
<td>Drug</td>
<td>Special warnings/ Precautions</td>
<td>Formulation and Route of Administration</td>
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<tr>
<td>Microtab</td>
<td>2mg nicotine bound to β-cyclodextrin as a complex</td>
<td>Nicotine sublingual tablet placed under the tongue. Nicotine absorbed via the buccal mucosa</td>
<td>1-2 microtabs per hour determined by smoker’s nicotine dependence (maximum 40 tabs per day)</td>
<td>Duration of treatment is individual, but at least 3 months of treatment is recommended. Gradually reduce dose by decreasing the total number of tablets used per day. Stop treatment when daily consumption is down to 1-2 per day</td>
</tr>
</tbody>
</table>
| Microtabs containing 2mg nicotine per cartridge | Cardiovascular disease  
GI Disease (including Peptic ulcer)  
Diabetes Mellitus  
Renal or hepatic impairment  
Phaeochromocytoma and uncontrolled hyperthyroidism  
Pregnant/breastfeeding *  
Those taking medication which may require dose adjustment | | |
| Nasal Spray | Small multi-dose bottle containing nicotine solution. The spray delivers 50μl of solution (0.5mg nicotine) per spray | 1 dose = 1 spray in each nostril | 12 week programme broken down as below |
| Nasal spray (10mg/ml) releasing 0.5mg nicotine per spray | Cardiovascular disease  
GI Disease (including Peptic ulcer)  
Diabetes Mellitus  
Renal or hepatic impairment  
Chronic nasal disorders  
Phaeochromocytoma and uncontrolled hyperthyroidism  
Bronchial asthma  
Pregnant/breastfeeding *  
Those taking medication which may require dose adjustment | Sprayed into the nostril. Nicotine rapidly absorbed through the thin nasal mucosa | 1-2 doses per hour as required determined by the smokers nicotine dependency. Maximum daily limit 64 sprays which is the equivalent of 2 sprays to each nostril every hour for 16 hours of the day.  
Reduce usage by half  
Reduce to zero by last day  
Spraying into a single nostril may be helpful in achieving this. Treatment should be limited to 3 months | 8 weeks  
2 weeks  
2 weeks |
<table>
<thead>
<tr>
<th>Drug</th>
<th>Special warnings/ Precautions</th>
<th>Formulation and Route of Administration</th>
<th>Dose and Frequency</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patch – 16 hr</strong></td>
<td></td>
<td>Self adhesive transdermal delivery system</td>
<td>1 patch per day</td>
<td>12 week programme broken down as below</td>
</tr>
<tr>
<td>Patches containing 25mg nicotine released over 16hrs</td>
<td>Cardiovascular disease</td>
<td>Self adhesive patch.</td>
<td>1 patch per day</td>
<td>8 weeks 15mg/16hr</td>
</tr>
<tr>
<td>Patches containing 15mg nicotine released over 16hrs</td>
<td>Diabetes Mellitus</td>
<td>A transdermal delivery system which slowly releases a controlled daily amount of nicotine into the skin.</td>
<td>1 patch per day</td>
<td>2 weeks 15mg/16hr</td>
</tr>
<tr>
<td>Patches containing 10mg nicotine released over 16hrs</td>
<td>Renal or hepatic impairment</td>
<td>To be applied on waking and removed at bedtime. Application limited to 16 hrs</td>
<td>1 patch per day</td>
<td>2 weeks 10mg/16hr</td>
</tr>
<tr>
<td><strong>Patch – 24 hr</strong></td>
<td></td>
<td>Self adhesive transdermal delivery system</td>
<td>1 patch per day</td>
<td>10 - 12 week programme broken down as below. (individual manufacturers vary)</td>
</tr>
<tr>
<td>Patches containing 21mg nicotine released over 24hrs</td>
<td>Cardiovascular disease</td>
<td>Self adhesive patch.</td>
<td>1 patch per day</td>
<td>4 weeks 21mg/24hr</td>
</tr>
<tr>
<td>Patches containing 14mg nicotine released over 24hrs</td>
<td>Diabetes Mellitus</td>
<td>A transdermal delivery system which slowly releases a controlled amount of nicotine into the skin.</td>
<td>1 patch per day</td>
<td>2 weeks 14mg/24hr</td>
</tr>
<tr>
<td>Patches containing 7mg nicotine released over 24hrs</td>
<td>Renal or hepatic impairment</td>
<td>To apply 1 patch soon after waking and wear continuously for 24 hrs then removeSkin site should not be reused for several days</td>
<td>1 patch per day</td>
<td>2 weeks 7mg/24hr</td>
</tr>
<tr>
<td>Drug</td>
<td>Special warning/ Precautions</td>
<td>Formulation and Route of Administration</td>
<td>Dose and Frequency</td>
<td>Duration</td>
</tr>
<tr>
<td>------</td>
<td>-----------------------------</td>
<td>----------------------------------------</td>
<td>-------------------</td>
<td>----------</td>
</tr>
<tr>
<td>Lozenge</td>
<td>Cardiovascular disease</td>
<td>1mg Lozenge</td>
<td>Nicotine absorbed via the buccal mucosa (Avoid acidic beverages, coffee and soft drinks 15 minutes before use) 1 lozenge every 1-2 hours normally 8-12 lozenges per day (maximum dose 25 lozenges per day)</td>
<td>Treatment time is individual normally continues for at least 3 months. Then gradually reduce number of lozenges and discontinue when the dose as been reduce to 1-2 per day.</td>
</tr>
<tr>
<td>Lozenge containing 1mg nicotine</td>
<td>GI disease</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diabetes Mellitus</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Renal or hepatic impairment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Phaeochromocytoma and uncontrolled hyperthyroidism</td>
<td></td>
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<td></td>
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<tr>
<td></td>
<td>Pregnant/breastfeeding</td>
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<td></td>
<td></td>
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<tr>
<td></td>
<td>Phenylketonuria</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sodium content</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Those taking medication which may require dose adjustment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lozenge containing 4mg, 2mg, or 1.5mg nicotine</td>
<td>2mg /4mg/1.5mg Lozenge</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Place in mouth and allow to dissolve. Periodically the lozenge should be moved from one side of the mouth to the other, and repeated, until the lozenge is completely dissolved.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Pregnancy and breast feeding are not listed as a special warning/precaution within NRT product licensing but have been included in the above list for the purpose of administering this scheme</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### AUTHORISATION

<table>
<thead>
<tr>
<th>Name of Community Pharmacy:</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Pharmacist(s) to whom this Voucher Scheme Service Level Agreement applies:</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>I (we) agree to participate in the NRT Pharmacy access Scheme when working for this Community Pharmacy:</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Name(s) of Pharmacist(s)</th>
<th>RPSGB registration Number</th>
<th>Signature(s) of Pharmacist(s)</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAPITALS</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pharmacy Specific Advice</th>
<th></th>
</tr>
</thead>
</table>

Pharmacies may wish to add here criteria specific to their own pharmacy e.g. Record keeping requirements. These are in addition to the Locally Enhanced Service

<table>
<thead>
<tr>
<th>Authorisation (from the owner, regional manager or superintendent pharmacist).</th>
<th></th>
</tr>
</thead>
</table>

I confirm that the pharmacy has sufficient indemnity insurance and attach a copy of the insurance certificate.

I hereby authorise the above named pharmacists to carry out this activity as stated in the Voucher Scheme SLA and will ensure that the service is provided as outlined in the SLA and associated appendices.

<table>
<thead>
<tr>
<th>For and on behalf of LCP CIC</th>
<th>For and on behalf of……………………… (Pharmacy name)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signed_______________________</td>
<td>Signed_______________________</td>
</tr>
<tr>
<td>Amina Hans-Adam</td>
<td>Name &amp; Position</td>
</tr>
<tr>
<td>Stop Smoking Specialist Advisor</td>
<td></td>
</tr>
<tr>
<td>Date__________________________</td>
<td>Date__________________________</td>
</tr>
</tbody>
</table>

A SLA does not remove inherent professional obligations or accountability. It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own code of professional conduct.
Voucher Scheme

Patient seen by Specialist Advisor or Pharmacy/Dental advisor - NRT voucher issued

Patient presents voucher to Pharmacy
Clinical assessment by pharmacist

Special precaution
Request a prescription from GP for 1st Supply of medication, subsequent supplies can be issued on vouchers

No precautions

No

Yes

NRT can be given

NRT cannot be given

Exempt / holds a prepaid Certificate
Client receives free NRT on completion of exemption declaration

Not Exempt
Client pays fee equivalent to current prescription charge

Pharmacist
Collects voucher and exchanges with NRT (Packaging must be labelled)

Pharmacist
Sends Yellow copy to Local Stop Smoking Service by the 5th of every month

Pharmacy reimbursed for NRT costs +5% & dispensing fee.
GOOD PRACTICE GUIDELINES FOR THE SAFE AND SECURE HANDLING OF VOUCHER PADS

1. Responsibility of the Individual Specialist/Intermediate advisor

Treat the Voucher pad as you would a cheque book:

**DO**

- Keep the pad with you in your bag or on your person whilst out of the office.
- Consider only taking one or two vouchers out with you.
- Secure the pad in a locked drawer in your place of practice when not in use.
- Record the number of the first and last voucher in each pad, and the date on which they were used. This can be done in your work diary.
- Notify your manager immediately if any forms or the pad go astray.
- Return all unused Vouchers to Locala SSS.
- Only use your own Voucher pad, and check it’s yours before writing on it.

**DON’T**

- Pre-sign blank Voucher forms.
- Leave the Voucher pad in your car
- Leave the Voucher pad unattended on your desk/counter
- Have more than one Voucher pad in use at any one time.
- Let any other practitioner use your Voucher pad.
- Use any other pad except your own - if you run out of Vouchers you will not be able to issue further vouchers until you get another pad!

2. Responsibility of LCP or Pharmacy/Dental Base

- Provide secure, lockable storage for Voucher pads.
- Ensure the provision of new Voucher pads as required.
- Minimise the risk of fraud by recording the numbers of the first and last Voucher in each pad on the Voucher pad record log.
- Inform LSSS with details of practitioners leaving pharmacy/dental practice.
- Retrieve unused voucher pads from advisors leaving LSSS/pharmacy/dental practice, or when voucher pads are no longer required (i.e. moving to a new role). ALL voucher pads MUST be returned to the LSSS. They should be annotated as returned on the voucher pad record log and re-issued as necessary.