Protocol for the direct supply of Nicotine Replacement Therapy (NRT)

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| Executive Director lead : | David Bridle – Interim Chief Medical Officer |
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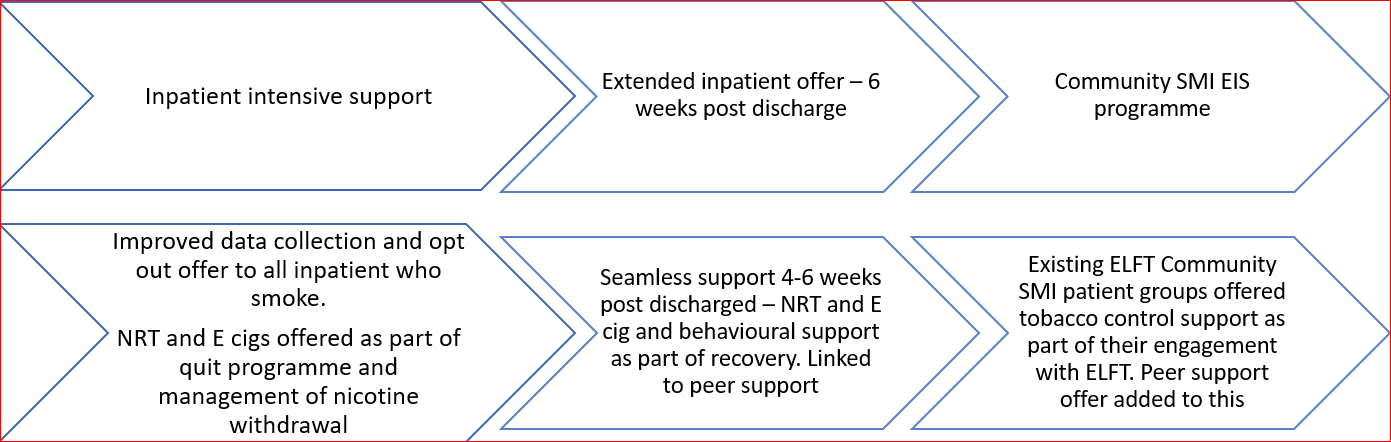
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| Services | Applicable |
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| Mental Health and LD |  |
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Version Control Summary

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| 1.0 | October 2022 | Chinedu Ogbuefi – Newham Lead Pharmacist | Final |  |

***Protocol for the direct supply of Nicotine Replacement Therapy (NRT)***

***S*cope:** For the treatment and management of nicotine withdrawal symptoms as part of the Smoking Cessation & Treatment Services at East London Foundation Trust. This is for community mental health service users, who are living in the community or linked to outpatient community mental health clinics as part of the early implementer programme to support smoking cessation. Please see below over view of ELFT Smoking service this protocol refers to the extended follow up 6 weeks post discharge and Community SMI Programme



***This is for East London Foundation Trust Registered Healthcare Professionals and Trained Smoking Cessation Advisors/Practitioners/Specialist Practitioners.***

**Overview**

This document authorises and sets out the condition under which nicotine replacement therapy (NRT) can be supplied directly to service users receiving stop smoking support from trained smoking cessation advisors in the community.

This protocol does not include Champix® and Bupropion. (Alternative provision is available through locality GPs)

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|  | **Requirements of Healthcare Professionals & Smoking Cessation Advisors working under the policy** |
| Qualifications and professional registration | Mandatory:   * NCSCT Stop Smoking Practitioner Training * NCSCT Stop Smoking Specialist Practitioner Training * NCSCT Stop Smoking SMI & Pregnancy Training   If Applicable:   * NMC Registration * HCPC Registration * UKPHR Registration * BPS Registration * GPhc Registration |
| Initial training | Smoking Cessation Practitioner & Specialist Smoking Practitioner Training |
| Competency assessment | Competency signed off by Smoking Cessation Lead |
| Ongoing training and competency | Smoking Cessation Practitioner & Specialist Smoking Practitioner Training.  Annual competency |
| Individual who is responsible for ensuring that all staff operating under this policy are trained and competent | Individual Staff and Line manager |

# Training and competency of registered health professionals and trained advisors who have completed the National Centre for Smoking Cessation and Training (NCSCT) <https://www.ncsct.co.uk/>

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| Clinical Condition/Indication | Smoking cessation and smoking reduction. |
| Clinical Situation to which this policy applies | Treatment of nicotine dependence and relief of withdrawal symptoms associated with smoking cessation.  The decision to use NRT must be guided by NICE/DH guidance depending on:   * Service User Preference * Service User previous experience of smoking cessation aids * Contraindications, cautions and the potential for adverse effects * Availability of smoking cessation counselling and support * Likelihood that the service user will follow the course of treatment |
| Inclusion Criteria | * Service users with severe mental illness (SMI) who are already being supplied with NRT whist in hospital as part of the planned programme to support tobacco abstinence. * Community ELFT service users who smoke tobacco products and require support for nicotine withdrawal. * Service users with severe mental illness (SMI) in the community with the motivation to quit smoking. |
| Exclusion Criteria | * Service users under Child and adolescent mental health services (CAMHs) * Non-smokers (individuals who have not smoked tobacco in the last 28 days). * Service users with chronic widespread skin disorders such as psoriasis, dermatitis or urticarial (Patches only). * Service users already using NRT, bupropion or Varenicline from another source. * Hypersensitivity to any component of the NRT product.   Applies to service users who:   * Have withheld consent. * Have had a previous reaction to NRT or any ingredients in the product1. * Have had a myocardial infarction1 or cerebrovascular accident1 in the last four weeks. * Have had a life-threatening cardiac arrhythmias1. * Have had a severe or worsening angina pectoris1. * Service Users prescribed aminophylline or theophylline. |
| Cautions | Refer to the British National Formulary or Summary of Product characteristics for further details of all products listed on page 3.  Service users prescribed methadone (due to the possible increase in methadone levels) or buprenorphine must be provided with NRT preparations via the Substance Misuse Service.  May cause palpitations (uncommon) in haemodynamically unstable and very rarely reversible atrial fibrillation (AF)  Unstable diabetes  Phaeochromocytoma  Hyperthyroidism  Hepatic/ Renal Impairment  Seizures  Gastrointestinal disease  Service users with recent history of myocardial infarction or cerebrovascular accident/ transient ischaemic attack  NRT must not be placed on broken or tattooed skin. |
| Special Considerations | * Service users prescribed methadone (due to the possible increase in methadone levels3) or buprenorphine must be provided with NRT preparations via the Substance Misuse Service. * Also, consider other medicines that interact with cigarette smoke (see Appendix 4) and liaise with medical team/non-medical prescriber regarding co-morbid conditions and/or adjustments to dosing of the medicines that interact with tobacco smoking. * Pregnant or breastfeeding women1. NRT is licensed for quit attempts. This protocol will also apply to patients attempting to reduce smoking. All pregnant or breastfeeding women should receive smoking cessation support. If the mother cannot (or is unlikely to quit without NRT support), NRT is recommended as the risk to the unborn baby is far lower compared to continuing to smoke. Those prescribing or supplying NRT should ensure that the potential risks and benefits are understood by the mother. The 24-hour patch should be taken off at night. Advise pregnant women who are using patches to remove them prior to bed (16 hour option is recommended where available). * Nicotine Liquorice Gum should not be used during pregnancy and lactation; however, ELFT does not offer this product. Pregnant women are advised to avoid Nasal Spray. A discussion on passive smoking should be held with the mother, a summary can be found here: <http://www.nhs.uk/conditions/pregnancy-and-baby/pages/smoking-pregnant.aspx> . Use of Varenicline or Buproprion is excluded. * Stable cardiovascular disease1 * Uncontrolled hypertension or cardiovascular event/hospitalisation for a cardiovascular complaint in the previous four weeks - Caution is advised due to limited evidence. Should be encouraged to stop smoking with non-pharmacological interventions such as counselling, however NRT products are less harmful than smoking and can be used. It is safer to use licensed nicotine-containing products than to smoke. Any risks associated with NRT are substantially outweighed by the well-established dangers of continued smoking NICE (2013). NRT is safe in patients with stable cardiovascular disease32. * Smokers currently hospitalised for a myocardial infarction, severe dysrhythmia (irregular heartbeat) or stroke and who are haemodynamically unstable (e.g. have a very low blood pressure), should initially be encouraged to quit without NRT. They should then be offered NRT under medical supervision. * Phaeochromocytoma and uncontrolled hyperthyroidism1. * Kidney or liver problems1 - NRT should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine and its metabolites may be decreased with the potential for increased adverse effects. * Diabetes (Additional glucose monitoring is required). (Advise the service user to be alert to signs of hypoglycaemia) 1. Smoking increases the risk for developing type 2 diabetes and is associated with complications of type 1 and type 2. Nicotine increases the release of catecholamines (e.g. adrenaline and noradrenaline), which can affect carbohydrate metabolism. Glucose levels should be monitored more closely in smokers and people using NRT. * For service users prescribed medicines listed under ‘special considerations’, the healthcare practitioner must liaise with the prescriber to ensure the appropriate guidelines are followed. * Swallowed nicotine (e.g. from gum or lozenges) may exacerbate oesophagitis, gastritis or peptic ulcers, therefore oral NRT preparations should be used with caution in these conditions. * Caution should also be taken for patients with Peripheral Vascular Disease and Occlusive peripheral Arterial disease.   **Cautions for patches only:**   * Occasional smokers should not require continual nicotine delivery, so should be offered a short acting preparation, such as an oral product. * Monitoring of sleep patterns for clients with sleeping problems if using the 24-hour patch. * Service users who have a chronic generalised skin disease such as psoriasis, chronic dermatitis and urticarial should not use a patch1. * Have had a previous reaction to a transdermal patch – if the service user prefers to continue to use a patch, an alternative brand must be sought, and the service user must be monitored closely. * If pregnant then advise to use a 16-hour patch or removal of a 24-hour patch before going to bed1. |
| **Additional information** | * The goal of this protocol is to ensure that all service users who are classified as a current smoker are offered the use of NRT when referred to smoking cessation service and when seen in community clinics. * The RIO forms, initial assessments and follow-up forms to be completed. * Offer behavioural support to people who smoke regardless of which option they choose to help them stop smoking. Explain how to access it. * For people with severe mental health conditions who may need additional support to stop smoking, offer:  1. Delivery by a specialist adviser with mental health expertise. 2. Support that is tailored in duration and intensity to the person's needs.  * Discuss ways of preventing a relapse to smoking. This could include talking about coping strategies and practical ways of making it easier to prevent a relapse to smoking. Do this at an early stage and at each contact Offer the opportunity for a further course of Varenicline, NRT or Bupropion to prevent a relapse to smoking. * Combination NRT must be considered for regular smokers who show high dependence or who found single forms inadequate in the past4. Nicotine overdose associated with NRT use in smokers is uncommon4, 7.Treatment doses must be reviewed if the service user experienced side effects from NRT and must be stopped if the service user experiences excessive side effects. The service user must be referred to the medical team. |
| **Action to be taken if service user is excluded from treatment** | * Record reason for exclusion. * Seek advice from service users’ medical team. * Document the action taken. * Advise on alternative options. * Provide behavioural support |
| **Action to be taken if the service user refuses treatment** | * Explanation of the benefits of controlling nicotine withdrawal symptoms. Ultimately patient choice * If appropriate, discuss with or refer to the service user's medical team. * Document that the service user refused treatment and action taken. * Continue to offer support during the course of their treatment, advising the service user that the option to be given nicotine replacement therapy is available at a later date if initially refused. * If service user would like support on discharge from inpatient services, please select the 'in house ELFT stop smoking service in their lifestyle assessment form on Rio. All referrals should be sent to [elft.stopsmoking@nhs.net](mailto:elft.stopsmoking@nhs.net). They will be supported in the community for up to 6 weeks then referred to their local community authority stop smoking service (based on their postcode) in line with information governance * For the Community Mental Health Team early implementer sites, service users with Serious Mental Illness (SMI) whom have not accessed in-patient services can be referred and will be seen/followed up for up to 12 weeks in line with 2021 NICE guidance. On discharge, they will be referred to their local community authority stop smoking service (based on their postcode) in line with information governance. |
| Arrangements for referral/liaison for medical advice | Practitioners to refer/liaise with GP or Psychiatrist for medical advice as required and appropriate. |
| Criteria for consideration to seek medical advice | When the following criteria apply, if needed, further medical advice should be sought in the first instance   * There is doubt whether an exclusion criterion applies * Service users taking theophylline, aminophylline, adenosine, clozapine, warfarin. * Service users who have experienced an acute cardiovascular event within the last 4 weeks * Service users with diabetes when initiating treatment * Service users with active peptic ulcer disease * Service users with a moderate or severe hepatic impairment * Service users with severe renal impairment * Service users with esophagitis * Service users with persistent cough or breathlessness |
| Duration of Therapy | * 6 weeks if therapy continued following initiation with service user as an inpatient at ELFT. * 12 weeks if therapy initiated in SMI patients in community. |

**Combination therapy**

Combination therapy is more effective than monotherapy and should be offered to all smokers (with clinical discretion) or people who have found NRT monotherapy insufficient in the past. Combination therapy is usually given as a long acting preparation and a short acting preparation to ‘top up’. Combination is supported by NICE.

The patch must be issued as described in the table below. The short acting preparations (i.e. Nicotine oral spray, nicotine inhalator or nicotine lozenges) should be used on as needed basis (up to the maximum dose described in this protocol) when acute withdrawal symptoms and urges to use tobacco occur.

**Nicotine – containing e-cigarettes**

Give clear, consistent and up-to-date information about nicotine- containing e-cigarettes to adults who are interested in using them to stop smoking.

Advise service users how to use nicotine-containing e-cigarettes. This includes explaining that:

* According to PHE and NICE, the use of E–cigarettes are 95% safer than cigarettes and more effective.
* E-cigarettes are not licensed medicines but are regulated by the Tobacco and Related products Regulations (2016).
* There is not enough evidence to know whether there are long-term harms from e-cigarette use.
* Any smoking is harmful so service users are encouraged to stop smoking tobacco completely when using e-cigarettes.
* Explain to service users who choose to use nicotine-containing e-cigarettes the importance of getting enough nicotine to overcome withdrawal symptoms and explain how to get enough nicotine

Discuss:

* How long the individual intends to use nicotine-containing e-cigarettes for
* Using them for long enough to prevent a return to smoking and
* How to stop using them when they are ready to do so

Ascertain from service user about any side effects or safety concerns that they may experience from using nicotine-containing e-cigarettes. Report these to MHRA Yellow Card scheme (<https://yellowcard.mhra.gov.uk/>) and let service users know that they can report side effects directly.

**Nicotine overdose/ toxicity**

Nicotine overdose from NRT products and e-cigarette is rare but still possible if not used appropriately.

**Signs and Symptoms for nicotine toxicity**

Early features of ingestion include burning in the mouth and throat, nausea, vomiting, confusion, dizziness, weakness, hypersalivation, sweating and increased bronchial secretions. There may be sympathetic features including tachycardia, tachypnoea, hypertension and agitation followed by bradycardia, systemic hypotension and respiratory depression. More severe poisoning can lead to arrhythmias including atrial fibrillation, coma, convulsions and respiratory and cardiac arrest.

Skin contact may lead to irritation with a level of absorption dependent on the length of exposure and concentration. Systemic features may follow.

**Table 1:** **Details of the Nicotine Replacement Therapy (NRT) medication**

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| **Name/Brand** | **Route** | **Dose of medication** | **Strength/ Administration** | **Benefits of use** | **Side effects, cautions and contraindications** |
| Nicotine Patch  Niquitin® Nicotinell® Nicorette® | Transdermal | Individuals who smoke more than 10 cigarettes daily should apply a high strength patch daily for 6-8 weeks, followed by the medium strength patch for 2 weeks, and then the low-strength patch for the final 2 weeks. Individuals who smoke fewer than 10 cigarettes daily can usually start with the medium strength patch for 6-8 weeks, followed by the low strength patch for 2-4 weeks; slower titration schedule can be used in individuals who are not ready to quit but want to reduce cigarette consumption before a quit attempt. If abstinence is not achieved or if withdrawal symptoms are experienced, the strength of the patch should be maintained or increased until the patient is stabilised. Individuals using the high strength patch who experience excessive side effects that do not resolve within a few days should change to a medium strength patch for the reminder of the initial period and then use the low strength patch for 2-4 weeks. | 16hour patches – 5mg, 15mg, 25mg  Apply once each morning to dry, clean, non-hairy area of skin (back, shoulder, upper arm or thigh and hold in place for 10-20 seconds. Wear for 16 hours. Never place on chest, abdomen or bottom. Remove used patch and dispose of safely. Next day, site the fresh patch on a different area. Allow several days before placing a patch on a previously used area  24 hour patches – 7mg,14mg, 21mg  Apply once each morning to dry, clean, non-hairy area of skin (back, shoulder, upper arm or thigh and hold in place for 10-20 seconds. Wear for 24 hours. Never place on chest, abdomen or bottom. Remove used patch and dispose of safely. Next day, site the fresh patch on a different area. Allow several days before placing a patch on a previously used area Note: 24 hour patches are best used by those who smoke firth thing in the morning and last thing at night. | Easy to use/ excellent safety profile | **General side effects of NRT:**  These are usually transient but may include the following, some of which are a consequence of stopping smoking: nausea, dizziness, headache and cold and influenza-like symptoms, palpitations, dyspepsia and other gastro-intestinal disturbances, hiccups, insomnia, vivid dreams, muscle pain; other side-effects reported include chest pain, reversible atrial fibrillation, blood pressure changes, anxiety and irritability, somnolence and impaired concentration, abnormal hunger, dysmenorrhoea, rash.  Specific side effects of patches:   * Insomnia (remove patch at night if affected). * Skin reactions:   Very common >1/10: itching.  Common ≥ 1/100 < 1/10: erythema.  Uncommon ≥ 1/1,000< 1/100: urticarial.  Discontinue use if severe or persistent. Another form of NRT can be used. |
| Nicotine Oral Spray  Nicorette Quick Mist® | Oral | 1-2 sprays as required Individuals can spray in mouth when the urge to smoke occurs or to prevent cravings, individuals should not exceed 2 sprays per episode (up to 4 sprays every hour); maximum 64 sprays per day. | 1mg/spray mouth spray-  The oral spray must be released into the mouth, holding the spray as close to the mouth as possible and avoiding the lips. The patient should not inhale while spraying and should avoid swallowing for a few seconds after use | Useful as part of combination therapy i.e. used with a nicotine skin patch or can be used as a sole | * Very common >1/10: Headache, Cough, Hiccups, Throat irritation, Nausea. * Common ≥ 1/100 < 1/10: Hypersensitivity, Burning sensation, Dizziness, Dyspepsia, Paraesthesia, fatigue, Abdominal pain, Diarrhoea, Dry mouth, Dyspepsia, Flatulence, Salivary hypersecretion, Stomatitis, Toothache, Vomiting. |
| Nicotine Inhalator  Nicorette® | Oral | As required, The cartridges can be used when the urge to smoke occurs or to prevent cravings, individuals should not exceed 12 cartridges of the 10mg strength daily or 6 cartridges of the 15mg strength daily. | 10mg and 15mg inhalator-Insert the cartridge into the device and draw in air through the mouthpiece; each session can last for approximately 5 minutes. The amount of nicotine from 1 puff of the cartridge is less than that from a cigarette; therefore, it is necessary to inhale more often than when smoking a cigarette. A single 15 mg cartridge lasts for approximately 40 minutes. Used cartridge must be disposed of via the waste bin. | Useful as part of combination therapy i.e. used with a nicotine skin patch or can be used as a sole | * Rhinitis. * Very common >1/10: coughing, irritation in throat and mouth. * Common ≥ 1/100 < 1/10: nausea, vomiting, nasal congestion. |
| Nicotine lozenges  Niquitin® Nicotinell® Nicorette® | Oral | 1 lozenge every 1-2 hours as required. 1 lozenge should be used when the urge to smoke occurs; individuals who smoke less than 20 cigarettes each day should usually use the lower strength lozenge. Individuals who smoke more than 20 cigarettes each day and those who fail to stop smoking with low strength lozenges should use the higher strength lozenges. If attempting smoking cessation, treatment should continue for 6-12 weeks before attempting a reduction in dose; maximum 15 lozenges per day | 1mg, 1.5mg, 2mg, 4mg lozenges  Each lozenge should be slowly dissolved in the mouth and periodically moved from one side of the mouth to the other. Lozenges last for 10–30 minutes, depending on their size. The lozenge should not be chewed or swallowed whole. Service users must be advised not to eat or drink while a lozenge is in the mouth. | Useful as part of combination therapy i.e. used with a nicotine skin patch or can be used as a sole to support the management of nicotine withdrawal symptoms | Very common >1/10: Sore mouth or throat, nausea, gastrointestinal upset, hiccups. Common ≥ 1/100 < 1/10: Vomiting, coughing.   * Uncommon ≥ 1/1,000< 1/100: Erythema, urticarial. * Rare ≥ 1/10,000 < 1/1,000: Allergic reactions including angioedema |
| Nicotine containing e-cigarettes (e-cig) | Oral | As required | Open the outer box of the e-cig and take out the disposable device. Remove and discard the silicon plug at each end of the device. Activate the vape by drawing on the end of the e-cig. An LED light will glow on the bottom of the e-cig. The LED light will flash when depleted-at this point, safely dispose of the device | Portable design, flavour range, convenient | **General side effects include**:  Cough, dizziness, dry/sore mouth and throat, headache, heart palpitations, shortness of breath, weakened taste, burning or scratching feeling in mouth, lips and throat  **Long-term adverse effects are unknown** |

For a comprehensive list of contraindications, interactions and side effects, refer to the manufacturer’s Summary of Product Characteristics.

Appendices**: Dosing schedules for nicotine replacement therapies**

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| **Appendix 1: Patches** | | | |
| **Patches** | **Nicotinell patches (24 hour patch)** | **Niquitin patches (24 hour patch)** | **Nicorette patches (16 hour patch)** |
| Smoking cessation schedule | >20 cigarettes/day -  21mg patch daily | >/=10 cigarettes/day -  21mg patch daily | >10 cigarettes/day -  25mg patch daily |
| < 20cigarettes/day  14mg patch daily | <10 cigarettes/day -  14mg patch daily | <10 cigarettes/day -  15mg patch daily |
| Duration of treatment | 3 - 4 weeks per strength | 21mg/day - 6 weeks  14mg/day – 2 weeks  7mg/day – 2 weeks  If starting at 14mg:-  14mg/day – 6 weeks  17mg/day – 2 weeks | 25mg/day – 8 weeks  15mg/day – 2 weeks  10mg/day – 2 weeks  If starting at 15mg:-  15mg/day – 8 weeks  10mg/day – 4 weeks |
| Total duration period | 3 months, but further treatments can be recommended if necessary. | 10 weeks (8 weeks if a light smoker). | As above |
| Maximum duration of treatment | Six months | Six months | Six months |
| Smoking reduction schedule | As above. | A patch can be used while the person continues to smoke. The person should reduce the number of cigarettes smoked as far as possible and make a quit attempt as soon as he/she feels ready. | Schedules as above. If the person reduces cigarettes to less than 10 cigarettes a day, the strength of the patch should be reduced to 15mg. A quit attempt should be made as soon as the person feels ready. |
| Excessive side effects | Reduce the strength of the patch for the remainder of the initial period and then use the low strength for 2-4 weeks. | Reduce the strength of the patch to 14mg for the remainder of the initial period and then use 7mg for 2 weeks. | Reduce the strength of the patch for the remainder of the initial period and then use the 10mg for 4 weeks. |
| Licence | Nicotinell patch is licensed for smoking cessation and smoking reduction. | Niquitin patch is licensed for smoking cessation and smoking reduction. | Nicorette patch is licensed for smoking cessation and smoking reduction. |
| Legal Classification  **POM/P/GSL/▲** | General sales list medicine | General sales list medicine | General sales list medicine |

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| **Appendix 2: Lozenges** | | | |
| **Lozenges** | **Nicotinell Lozenge** | **Niquitin Lozenge** | **Nicorette Lozenge** |
| Smoking cessation schedule | >30 cigarettes a day, 2mg nicotine lozenge is indicated.  </=20 cigarettes per day.  20 – 30 cigarettes /day, 1mg or 2mg are acceptable.  <20 cigarettes per day, 1mg is indicated. | >20 cigarettes per day - 4mg are acceptable.  </=20 cigarettes per day, 1.5mg is indicated.  Sufficient lozenges should be used each day to a maximum of 15 per day. | >20 cigarettes a day, 4mg lozenge is indicated.  </=20 cigarettes per day 2mg nicotine gum.  The lozenge should be used whenever the urge to smoke is felt or to prevent cravings in situations where these are likely to occur. |
| Duration of treatment | After three months, the user should gradually cut down the number of pieces sucked each day until they have stopped using the product. | After six weeks, the user should gradually cut down the number of pieces sucked each day until they have stopped using the product. | As below. |
| Maximum duration of treatment | Six months | Six months | Six months |
| Smoking reduction schedule | As above. | The lozenge should be used as needed, between smoking episodes with the intention to reduce smoking as much as possible. | The lozenge should be used as needed, between smoking episodes with the intention to reduce smoking as much as possible. |
| Maximum daily dose | 1mg – 30 pieces per day  2mg – 15 pieces per day.  1mg lozenge may be helpful when stopping treatment or reducing the number of gums used each day). | 15 pieces per day. | 15 pieces per day.  (2mg lozenge may be helpful when stopping treatment or reducing the number of gums used each day). |
| Licence | Nicotinell lozenge is licensed for smoking cessation and smoking reduction. | Niquitin lozenge is licensed for smoking cessation, smoking reduction and gradual cessation of smoking. | Nicorette lozenge is licensed for smoking cessation and smoking reduction. |
| Legal Classification  **POM/P/GSL/▲** | General sales list medicine | General sales list medicine | General sales list medicine |

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| **Appendix 3: Miscellaneous NRT** | | |
| **Miscellaneous** | **Inhalator** | **Mouth spray** |
| Smoking cessation schedule | Smokers willing/able to stop smoking immediately should replace all their cigarettes with the Inhalator and as soon as they are able, reduce the number of cartridges used until they have stopped. | Patients can use 1-2 sprays in the mouth when the urge to smoke occurs or to prevent cravings. Individuals must not exceed 2 sprays per episode (4 sprays per hour), |
| Duration of treatment | Use 1 – 6 cartridges daily for 4-8 weeks.  Then reduce to 1-3 cartridges over the next 2 weeks.  Then reduce to zero over 2 weeks. | 2 sprays up to twice an hour for 16 hours a day as required – for 8 weeks  Half usage – for two weeks  Reduce usage to zero – for two weeks. |
| Smoking reduction schedule | Smokers aiming to reduce cigarettes should use the Inhalator, as needed, between smoking episodes with the intention to reduce smoking as much as possible5. Each cartridge can be used for approximately eight 5-minute sessions, with each cartridge lasting approximately forty minutes of intense use. | Smokers aiming to reduce cigarettes should use the mouth spray, as needed, between smoking episodes to prolong smoke-free intervals and with the intention to reduce smoking as much as possible. As soon as they are ready, smokers should aim to quit. |
| Maximum daily dose | 6 cartridges in 24 hours | 64 sprays in 24 hours |
| Licence | The inhalator is licensed for smoking cessation and smoking reduction. | The mouth spray is licensed for smoking cessation and smoking reduction. |
| Legal Classification  **POM/P/GSL/▲** | General sales list medicine | General sales list medicine |

**Appendix 4: Psychotropic drugs affected by smoking status (Maudsley, 14th Ed, page 856)**

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| **Drug** | **Effect of smoking** | **Action to be taken on**  **stopping smoking** | **Action to be taken on**  **re-starting** |
| **Aminophylline** | Plasma levels reduced | Monitor closely, consider  dose reduction | Monitor closely, consider  restarting previous smoking  dose |
| **Agomelatine** | Plasma levels reduced | Monitor closely  Dose may need to be  reduced | Consider reintroducing  previous smoking dose |
| **Benzodiazepines** | Plasma levels reduced by  0–50% (depends on drug  and smoking status) | Monitor closely  Consider reducing dose  by up to 25% over one  week | Monitor closely  Consider re-starting  ‘normal’ smoking dose |
| **Carbamazepine** | Unclear, but smoking may  reduce carbamazepine  plasma levels to a small  extent | Monitor for changes in  severity of adverse effects | Monitor plasma levels |
| **Chlorpromazine** | Plasma levels reduced.  Varied estimates of exact effect | Monitor closely, consider  dose reduction | Monitor closely, consider  restarting previous smoking  dose |
| **Clozapine** | Reduces plasma levels by  up to 50%  Plasma level reduction  may be greater in those  Receiving valproate. Effect  is reversed by  co-administered  fluvoxamine | Take plasma level before  Stopping. On stopping,  reduce dose gradually  (over a week) until around  75% of original dose  reached (i.e. reduce by  25%). Repeat plasma  level one week after  Stopping. Anticipate  further dose reductions | Take plasma level before  Re-starting. Increase dose to  previous smoking dose over  One week. Repeat plasma  Level. Deterioration is  common if dose increases  allow a fall in blood levels13 |
| **Doxepin** | Plasma levels reduced by  around 25% (levels of  nordoxepin metabolite  increased) | Monitor closely  Dose may need to be  reduced | Consider reintroducing  previous dose |
| **Duloxetine** | Plasma levels may be  reduced by up to 50% | Monitor closely  Dose may need to be  reduced | Consider reintroducing  previous smoking dose |
| **Escitalopram** | In practice smokers have  lower blood levels despite  being given higher doses  Reduction in levels may be  up to 50% (possibly via  induction of CYP2C19) | Monitor closely  Consider 25% dose  reduction | Monitor closely  Reinstate smoking dose |
| **Fluphenazine** | Reduces plasma levels by  up to 50% | On stopping, reduce dose  By 25%. Monitor carefully  Over following 4–8 weeks.  Consider further dose  reductions | On re-starting, increase  dose to previous smoking  dose |
| **Fluvoxamine** | Plasma levels decreased by around a third | Monitor closely  Dose may need to be  reduced | Dose may need to be  increased to previous level |
| **Haloperidol** | Reduces plasma levels by  around 25–50% | Reduce dose by around  25%. Monitor carefully.  Consider further dose  reductions | On re-starting, increase  dose to previous smoking dose |
| **Loxapine** (inhaled) | Half-life reduced from  15.7 hours to 13.6 hours | Monitor | Monitor |
| **Mirtazapine** | Unclear, but effect  probably minimal | Monitor | Monitor |
| **Olanzapine** | Reduces plasma levels by  up to 50%  Discuss with prescribing Clinician | They can consider taking plasma level before Stopping and after as required and appropriate.  On stopping, the does may be reduced by 25% by the prescribing clinician. | Monitor closely , |
| **Risperidone/ paliperidone** | Active moiety  concentrations probably  lower in smokers  Minor effect  (possibly via induction of  CYP3A4) | Monitor closely | Monitor closely |
| **Trazodone** | Around 25% reduction | Monitor for increased  Sedation. Consider dose  reduction | Monitor closely. Consider  increasing dose |
| **Tricyclic antidepressants** | Plasma levels reduced by  25–50%. | Monitor closely. Consider  reducing dose by 10–25%  Over 1 week. Consider  further dose reductions | Monitor closely. Consider  restarting previous smoking  dose |
| **Zuclopenthixol** | Unclear, but effect  probably minimal | Monitor | Monitor |

Note: Only cigarette smoking induces hepatic enzymes in the manner described above – nicotine replacement, vaping.

Devices and electronic cigarettes (which do not contain polycyclic aromatic compounds) have no effect on enzyme activity

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| **Appendix 5: Treatment Directive** | |
| **Name, form and strength of medicine** | Nicotine replacement therapy products as listed in the table 1 |
| **Is the medicine to being used within its UK product license? If not, please list references to support its place in clinical practice** | Yes  No (For nicotine containing e-cigarettes) |
| **Route/ method of administration** | Transdermal patch, oral |
| **Dose and frequency** | As per manufacturers’ instructions |
| **Quantity to be supplied** | 4 weeks’ worth |
| **Maximum treatment period** | 12 weeks |
| **Monitoring required e.g. BP, Pulse, Temperature** | Carbon monoxide testing |
| **Adverse effects** | See table 1 |
| **Records to be kept** | These must allow the use of the protocol to be audited  The issue of NRT products to be recorded in the electronic patient record (RiO)   * Date/ time of supply and/or administration * Patient details – name, date of birth, RiO/NHS number * Details of medicine – name, strength, dose, frequency, route, batch number and quantity supplied * Name and signature of smoking advisor issuing NRT treatment |

**Patient Information**

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| **Written information to be given to service user or carer** | Each box of the products comes with a patient information leaflet and the whole box is issued with the leaflet enclosed |
| **Follow-up advice to be given to the patient or carer** | All patients given medication under this protocol should have the following information discussed with them   * What the medicine is, how to use it and the intended benefits * Likely adverse effects and what to do if they are experiencing them * What to do if they miss a dose * Whether another NRT is needed and how to get further supplies |

**Appendix 6: Healthcare professionals and smoking advisors agreement to practice**

Healthcare professional or smoking cessation advisor:

I have read and understood this protocol and agree to supply and/or administer these products in accordance with this protocol.

Senior representative:

I confirm that the individual named meets the criteria listed in ‘Training and competency of registered healthcare professionals/ smoking cessation advisors and has completed all the required training and assessment of competency.

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| --- | --- | --- | --- | --- | --- |
| **Detail of healthcare professional/smoking cessation advisor** | | | **Details of authorising senior representative** | | |
| **Print Name** | **Signature** | **Date** | **Print Name** | **Signature** | **Date** |
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