

**PROTOCOL FOR  
NICOTINE REPLACEMENT THERAPY (NRT)  
and/or  
E-cigarette (EC)  
VOUCHER SCHEME**

**FIRST ISSUED: 1<sup>st</sup> June 2019**

**TO BE REVIEWED: 31<sup>ST</sup> March 2023**

**Please note:** this scheme does NOT apply to Varenicline (Champix) & Bupropion (Zyban) – both are Prescription Only Medicines (POMs).

## **Introduction**

The aim of the voucher scheme is to enable clients to easily access NRT or EC when attending a stop smoking programme. Standard operating procedures (SOPs) and clinical governance processes should be set up and adhered to at all times to assure patient safety

All NRT products are classified as General Sales List products, there are currently no EC licensed by the Medicines and Healthcare products Regulatory Agency (MHRA) but are regulated in the Europe Union under Article 20 of the Tobacco Directive (2014/14/EU). NRT and/or EC can be supplied directly from pharmacies or Vape shops approved by Birmingham City Council. They can therefore be supplied directly from pharmacies or other licensed premises without a prescription. The voucher is issued by a stop smoking practitioner who assesses suitability of clients.

Under the scheme, the stop smoking practitioner recommends the supply of NRT/EC using a voucher that is taken to the participating pharmacy of the client's choice. Product selection is based on a discussion between the client and the practitioner, the range available and consideration of potential contra-indications. The pharmacist makes the final decision as to whether NRT/EC can be dispensed to the client (or in rare circumstances can recommend an alternative form after discussing it with the client and the practitioner who made the initial recommendation).

Vouchers for NRT/EC can be accepted at any participating pharmacy within Birmingham.

## **Who can issue the voucher?**

A trained stop smoking practitioner contracted and signed up to deliver smoking cessation with Birmingham City Council can issue vouchers to the clients they are supporting.

Please note that practitioners do not have to be from a clinical background but must be NCSCT certified and keep their knowledge and skills up to date to recommend NRT/EC supply under this protocol.

## **When should the voucher be issued?**

- When a client is motivated to quit
- After background information has been attained, and any relevant medication assessment (see [Appendix 1](#)) has been taken and documented. Any necessary information, including any other medication currently being taken by the client (see [Appendix 2](#)), should be identified on the voucher for the pharmacist to aid their assessment before they agree to administer NRT/EC
- After agreement with the client of the most clinically appropriate choice of NRT/EC
- After the client has been made aware of the potential side effects of stopping smoking (see [Appendix 3](#))
- When the client has decided on a firm quit date and it is recorded accordingly
- When no contra-indications of NRT/EC are present

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- Practitioners should keep up to date with their knowledge on medications. This can be done by searching the latest summary of products and characteristics (SPC) of each individual NRT all of which are available on the [NCSCT website](#)<sup>1</sup>.

## How to complete the voucher

### Instructions for completing voucher

- Enter voucher code/week number.
- Enter client details.
- Enter your details, sign and date issued.
- Select NRT/EC (tick box)

## When the voucher has been filled in:

- The voucher will be given to the client by the practitioner to take to the pharmacy
- Inform the client to take the voucher to their participating pharmacy to collect their medication
- The pharmacist will enter the information onto PharmOutcomes as proof of dispensing
- The pharmacist will check the completed exclusion criteria (see [Appendix 1](#)) and comments box. If they agree with the supply, they will record NRT/EC products on PharmOutcomes and dispense the NRT/EC
- Before the supplies are dispensed, the pharmacist must ensure that the voucher has been fully completed by the stop smoking practitioner
- In case of query, Rachel Hill can be contacted on Tel: 0121 303 4127  
Email: [Rachel.hill@birmingham.gov.uk](mailto:Rachel.hill@birmingham.gov.uk) Or contact the practitioner who issued the voucher.
- Posting vouchers to clients should only be done in extreme circumstances. **Note:** this should only happen in exceptional circumstances where the client cannot be seen in person

## Period of administration for the voucher:

This will be determined by the practitioner using their clinical judgment and assessment of the client but will normally follow these guidelines:

- Vouchers may only be supplied when the client has set a quit date.
- Clients will be invited to attend for ongoing support up until CO validation at 12 weeks.
- The initial voucher should be issued for one week only. Further vouchers should continue to be supplied in 1 or 2 weekly alongside regular behavioural support sessions and only issued if the client remains abstinent.
- If the client is abstinent at 4 weeks (and preferably CO validated) NRT/EC can continue to be supplied alongside behavioural support to a maximum of 12 weeks.
- The supply of vouchers may be discontinued at any stage of a client's quit attempt at the discretion of Birmingham City Council.

## Exceptions to the two weekly dispensing:

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<sup>1</sup> <http://www.ncset.co.uk/>

- If a client is going on holiday or is unable to attend, the next voucher can be issued for a further two weeks. This should only be for extenuating circumstances and will also be dependent on the progress of the quit attempt
- The voucher can be post-dated or the two vouchers can be issued for the same date
- The reason must also be clearly stated on the voucher to make the pharmacist aware of why the practitioner has issued two vouchers together. This should then be recorded on the PharmOutcomes template.

### **The amount of NRT/EC per voucher:**

- A maximum of four product items can be recommended on one voucher
- It is recommended that the maximum dosage should be dispensed on the first voucher, including a second product for combination therapy (depending on suitability). This can then be reviewed in following sessions to check the usage and dispense accordingly
- The total prescribed should not exceed 2 weeks

### **Advice to clients:**

Clients should be given specific product advice and the Nicotine Replacement Therapy Product Information Leaflet (within the original NRT pack) plus the following general advice on:

- Withdrawal symptoms and how to manage these
- The effects of smoking tobacco whilst using NRT/EC
- Appropriate self-help leaflets
- The importance of follow-up appointments and review of the NRT/EC
- How to obtain further supplies of NRT/EC
- Effects of nicotine on unborn babies versus continuing to smoke enabling clients to make an informed decision on risk
- **EC cannot be issued to under 18yr or pregnant women**

### **How much will NRT cost?**

If the client pays for prescriptions:

- The client will pay a single prescription charge for 12 week supply of NRT/EC
- The Declaration of Exemption section should be crossed through
- Collect any NHS fees (equivalent to the standard prescription charge)

If the client does not pay for prescriptions:

- No charge will be incurred by the client
- The pharmacist must check proof of exemption

### **Limited time value of the voucher:**

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- The practitioner should inform the client that they must present the voucher to a pharmacist within 28 days of issue. Any attempts to redeem after that will result in refusal
- All practitioners must make sure they complete the voucher correctly with the date of issue completed
- Pharmacists must ensure that the issue date is completed and that the voucher is presented within the 28 day time scale.
- Photocopies of vouchers cannot be accepted; they must be the original document and signed by the practitioner in indelible ink

#### **Protocols for safe-keeping of referral/vouchers if used:**

- Electronic Vouchers can be found on the practice clinical system, if paper copies are used then the voucher should be stored in a locked cupboard
- All vouchers are individually numbered
- They should never be transferred to anyone else, remaining the property of Birmingham City Council.
- Paper copies only: If voucher are no longer required for any reason then they should be returned to the following address – Public Health, Birmingham City Council, P.O.Box 16732, Birmingham, B2 2GF

#### **Loss or theft of vouchers:**

In the event of loss or theft of any vouchers the following action should be taken:

- Report the loss to Rachel Hill:
- Tel: 0121 303 4127
- Email: Rachel.hill@birmingham.gov.uk
- Rachel will alert the pharmaceutical lead and risk management team providing details of numbers of the vouchers
- Arrangement will be made to circulate these details to all pharmacists

#### **Details of record keeping**

- Records must be kept for at least two years

### Reimbursement to pharmacies:

- A professional flat rate of **£4** is paid for each voucher transaction
- The pharmacy is reimbursed at the **drug tariff price plus VAT at 20%** for the NRT product supplied. Where a product is not listed in the drug tariff, the **trade price plus VAT at 20%** in chemist and druggist will be paid

### NRT available through the voucher scheme

- **Patches**
  - Nicotine 21mg/24 hour
  - Nicotine 14 mg/24 hour
  - Nicotine 7mg/24 hour
  - Nicotine 25mg/16 hour
  - Nicotine 15mg/16 hour
  - Nicotine 10mg/16 hour
  - Nicotine 15mg/16 hour patch
  - Nicotine 10mg/16 hour patch
- **Gum**
  - Nicotine 6mg
  - Nicotine 4mg
  - Nicotine 2mg
- **Lozenge**
  - Nicotine 4mg mini-lozenge
  - Nicotine 4mg Cools lozenge
  - Nicotine 2mg Cools lozenge
  - Nicotine 1.5mg mini-lozenge
- **Inhalator**
  - Nicotine 15mg inhalator
- **Mouth Spray**
  - Nicotine 1mg/spray mouth spray
- **Oral Strip**
  - Nicotine 2.5mg Oral strip

**All supplies:**

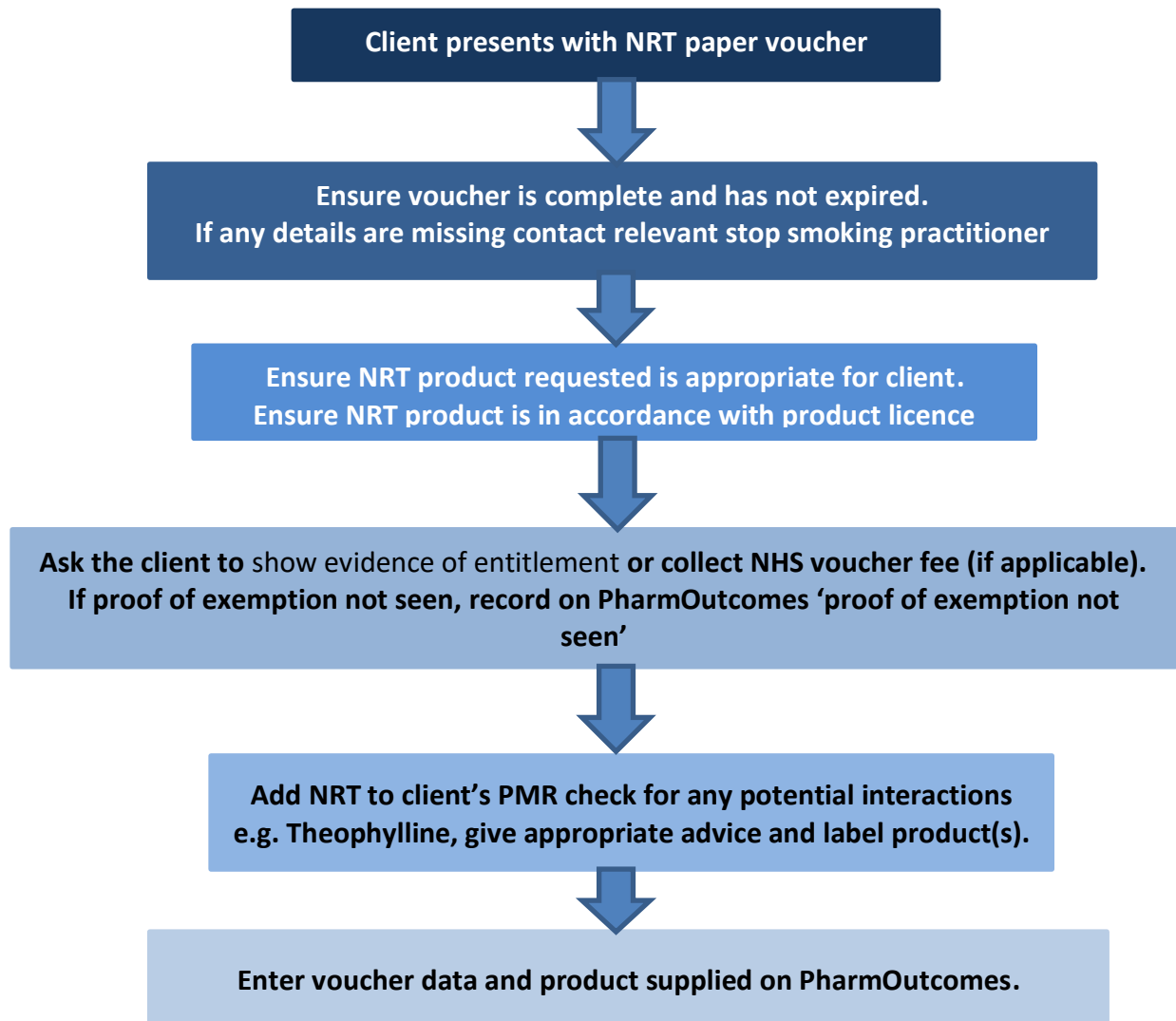
Maximum length of treatment is normally 12 weeks (NICE 2002)

All products on the formulary should be made available by the pharmacist at any time. It is the pharmacist's responsibility to ensure that these products are in stock, unless there is a manufacturer supply problem.

**Instructions for dispensing voucher**

1. Check date issued. **IMPORTANT:** If client has brought paper voucher in to be redeemed, check that the date issued is within 28 days. If over 28 days, the voucher is void. Request client to contact the trained stop smoking practitioner that supplied the voucher.
2. Check NRT requested by the stop smoking practitioner is in accordance with the exclusion criteria
3. Check any comments from the practitioner
4. Enter voucher details onto PharmOutcome template including NRT brand, name, pack size and number of packs given.
5. The pharmacy must ask any person who makes a declaration that they are exempt from paying prescriptions to produce satisfactory evidence of such entitlement.
6. If client pays prescription fees, collect prescription charge and record on PharmOutcomes.

**Standard Operating Procedure Flowchart for the supply of NRT in Accordance with Service Specifications for the NRT Voucher Scheme within participating Pharmacies**





## Appendix 2– Inclusion and exclusion criteria

### Inclusion criteria

- Clients identified as sufficiently motivated to quit (i.e. willing to set a quit date and receive weekly support for the first 4 weeks)
- Adolescents (12 - 18) and are motivated to quit. (Maximum of 12 weeks treatment)
- Patients who have been hospitalised due to a cardiovascular/cerebrovascular event (MI, severe dysrhythmias, cerebrovascular accident) or those considered hemodynamically unstable who have had their first supply of NRT prescribed by a medical practitioner.
- NRT can be provided to women who are pregnant and breast feeding. However, before making a decision, the stop smoking adviser will discuss the risks of smoking versus the benefits of NRT with the client.

### Exclusion criteria

- Tobacco users not sufficiently motivated to quit or use NRT
- Tobacco users under the age of 12
- Clients with severe cardiovascular disease. This is defined as patients with acute, unstable or poorly controlled disease i.e. more than three episodes of angina per week (SMPCT CHD NSF steering group January 2009).
- Clients with history of recent cerebrovascular accident. 'Recent' is defined as less than 4 weeks (British National Formulary 62 September 2011)
- Clients with previous serious reaction to NRT or any the other ingredients contained in the products e.g. glue in patch
- **Patches only** - clients with chronic generalised skin disease such as psoriasis, chronic dermatitis, and urticaria: clients who have had a previous reaction to transdermal patches: occasional smokers.
- Clients using NRT products who have relapsed and returned to smoking. Further NRT products should not be supplied until a new quit date is set
- Where intervention with Zyban (bupropion) or Champix (varenicline) might be more appropriate

### **Appendix 3 - Drug interactions**

Many commonly used medicines are substrates for CYP1A2: theophylline; fluvoxamine; caffeine; coumarins, including warfarin; and the antipsychotics clozapine and olanzapine. However, not all possible drug-smoking interactions are clinically significant.

### **Appendix 4 - Side Effects**

These are usually transient but may include the following, some of which are a consequence of stopping smoking:

nausea, dizziness, headaches, cold and flu-like symptoms, palpitations, dyspepsia and other gastro-intestinal disturbances, hiccups, insomnia, vivid dreams, myalgia, chest pain, blood pressure changes, anxiety and irritability, somnolence and impaired concentration, dysmenorrhoea.

Refer to summary of product characteristics and package insert for details on [product-specific side effects](#)<sup>1</sup>.

Clients experiencing minor side effects should be offered symptomatic advice and encouraged to persevere with treatment/cessation.

Clients experiencing severe side effects should be advised to stop treatment and to see their GP for further advice.

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<sup>1</sup> <http://www.medicines.org.uk/emc/>