

PROTOCOL FOR A NICOTINE REPLACEMENT THERAPY (NRT) VOUCHER SCHEME

PREPARED BY: Kirklees Public Health on behalf of the
Council of the Borough of Kirklees

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ISSUED TO: Community Pharmacists in the Kirklees
District

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

1. Introduction

All NRT products are classified as General Sales List products. They can therefore be supplied directly from pharmacies or other licensed premises without a prescription. The voucher is normally issued by a stop smoking practitioner who assesses suitability of clients. The NRT is issued by a pharmacist.

The aim of the voucher scheme is to enable clients to easily access NRT 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.

Under the scheme, the stop smoking practitioner recommends the supply of NRT 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 can be dispensed to the client (or in rare circumstances can recommend an alternative form after discussing it with the client & the practitioner who made the initial recommendation).

Vouchers for NRT can be accepted at any participating pharmacy within Kirklees.

2. Who can issue the voucher?

A trained stop smoking practitioner working on behalf of an organisation contracted and signed up to deliver smoking cessation with Kirklees 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, have received face-to-face training in line with the NCSCT training standards and keep their knowledge and skills up to date to recommend NRT supply under this protocol.

3. 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
- After agreement with the client of the most clinically appropriate choice of NRT

- 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 are present

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](#)¹.

4. How to complete the voucher

Instructions for completing voucher

1. Circle appropriate voucher number. This is to monitor how many vouchers have been given in an episode of care.
2. Enter client details.
3. Enter your details, sign and date issued.
4. Select NRT (tick box).

Keep one copy for your records (white copy) and give the other 2 copies (pink and yellow) to the client.

When the voucher has been filled in:

- Check that the carbon has worked and that all three copies are complete and clearly legible
- The second and third copy will be given to the client by the practitioner to take to the pharmacy.
- The pharmacist will retain one copy for their records and return one to Kirklees Public Health Commissioning Team as proof of dispensing. The first copy will be kept by the stop smoking practitioner as proof of recommendation.
- Inform the client to take the voucher to their participating pharmacy to collect their medication
- The pharmacist will check the completed exclusion criteria (see [Appendix 1](#)) and comments box. If they agree with the supply, they will record NRT products on client's Patient Medication Record (PMR), label products and dispense the NRT
- 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, Vicki Stadnicki can be contacted on
 - Tel: 01484 221000
 - Email: vicki.stadnicki@kirklees.gov.uk
 or contact the practitioner who issued the voucher.

¹ <http://www.ncset.co.uk/>

- 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 weekly support up until CO validation at 4 weeks post quit.
- The initial NRT voucher should be issued for one week only. Further NRT vouchers should continue to be supplied in 1 weekly amount for 4 weeks and then 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 can continue to be supplied alongside behavioural support to a maximum of 12 weeks.
- In Pregnancy, if a client has not quit by the end of the 4th week of patches, these will be withdrawn, and the client will be reassessed for readiness to quit in a month's time.
- The supply of vouchers may be discontinued at any stage of a client's quit attempt at the discretion of the specialist advisor.

Exceptions to the two weekly dispensing:

- 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 depend 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.

The amount of NRT per voucher:

- A maximum of two 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
- Appropriate self-help leaflets
- The importance of follow-up appointments and review of the NRT.
- How to obtain further supplies of NRT
- Effects of nicotine on unborn babies versus continuing to smoke enabling clients to make an informed decision on risk

5. How much will NRT cost?

Clients will pay a prescription charge for each NRT product.

- **If the client pays for prescriptions:**
 - The client will pay for supply of each recommended product, for every voucher.
 - 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
 - All clients who are exempt must sign the Declaration of Exemption section on the voucher and indicate which category makes them exempt
 - Where clients are exempt from prescription charges, they must tick the appropriate box on the voucher under exemption categories and sign the declaration
 - The pharmacist must check proof of exemption

Limited time value of the voucher:

- 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

6. Protocols for safe-keeping of referral/voucher pads if used:

- Voucher pads should be stored in a locked cupboard when not in use
- All vouchers are numbered and allocated to a practitioner
- They should never be transferred to anyone else, remaining the property of Kirklees Public Health.
- Practitioners should keep a record of their allocated batch number

- If voucher pads are no longer required for any reason then they should be returned to the following address – **Kirklees Public Health, 4th Floor North, Civic Centre 1, High Street, Huddersfield, HD1 2NF.**

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 Vicki Stadnicki:
 - Tel: 01484 221000
 - Email:vicki.stadnicki@kirklees.gov.uk
- Vicki Stadnicki 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.

7. Reimbursement to pharmacies:

- A professional fee of **£3** is paid for each voucher presented
- 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

8. NRT available through the voucher scheme

• Patches

- Nicotine 21mg/24 hour
- Nicotine 14 mg/24 hour
- Nicotine 7mg/24 hour
- Nicotine 25mg/16 hour Invisipatch
- Nicotine 15mg/16 hour Invisipatch
- Nicotine 10mg/16 hour Invisipatch
- 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:

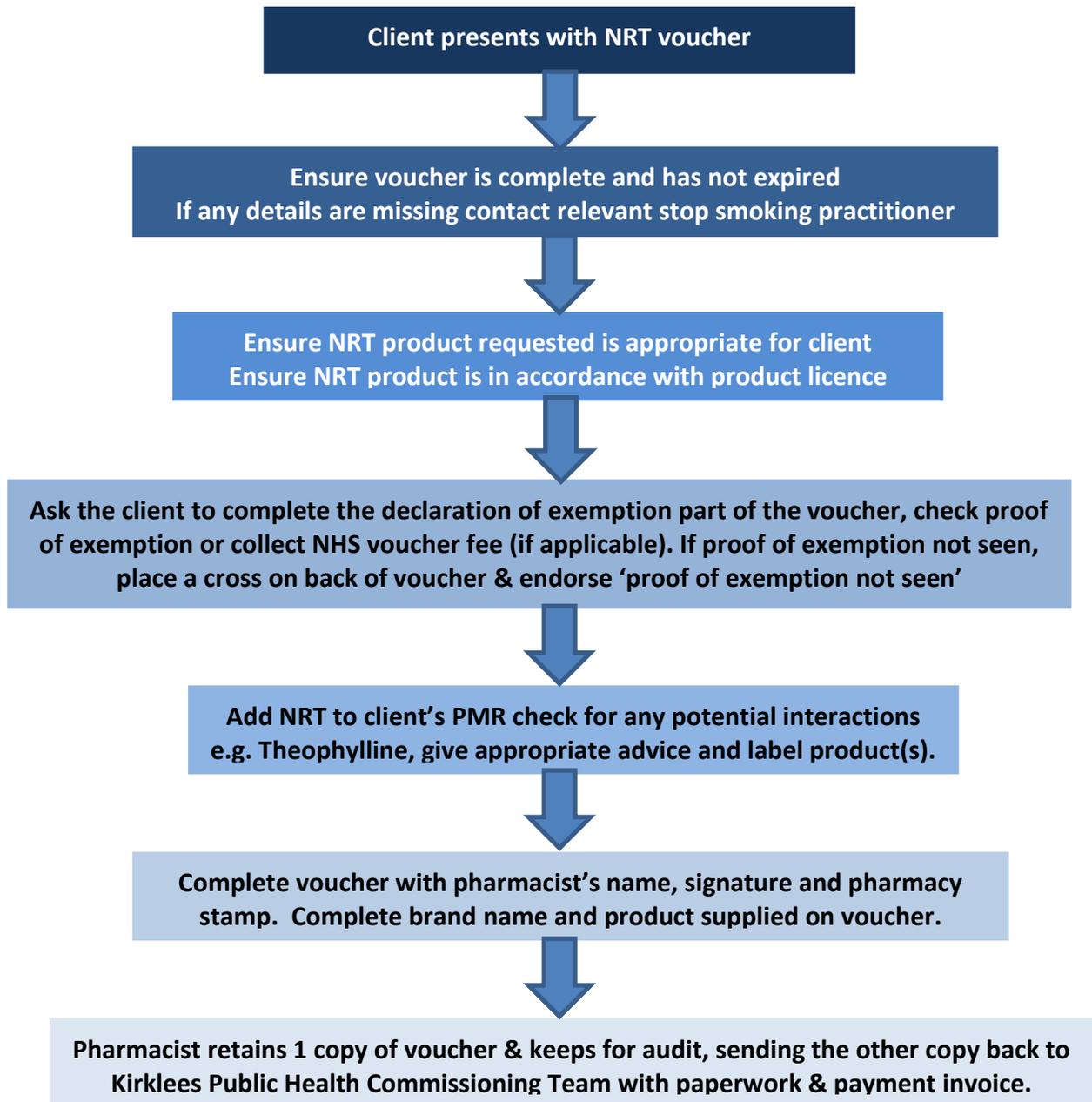
Maximum length of treatment is normally 12 weeks (NICE 2002)

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 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. Add to clients Patient Medication Record (PMR) and label products. Dispense medication and complete section "**Pharmacist Use Only**", listing the product brand name, pack size and number of packs given
5. If client is exempt from prescription fees, they need to complete part 1, read the declaration and complete part 3.
6. If client pays prescription fees, complete parts 2 and 3.
7. Keep one copy, other copy to be returned to Kirklees Public Health Commissioning Team along with client file returns when invoicing. This will be your proof of dispensing and to claim any remuneration.

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



Appendix 1 – 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 2 - 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 3 - 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](#)².

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.

² <http://www.medicines.org.uk/emc/>