



**Protocol for the
Direct Supply of Nicotine Replacement
Therapy
by Competent Non-Clinical
Advisors of
The Stop Smoking Service in Norfolk**

Document Control

• Document name	Protocol for the direct supply of Nicotine Replacement Therapy by Competent Non-Clinical Advisors of the Norfolk Stop Smoking Services
• Date authorised	•
• Valid from	• 1 st April 2017
• Planned review dates	• 1 st April 2019

Overview

This document authorises and sets out the conditions under which nicotine replacement therapy (NRT) can be supplied directly to clients receiving stop smoking support from accredited advisors who are expected to provide Stop Smoking Services as part of the Norfolk Stop Smoking Service.

1. Scope and Focus

1.1 Name of authorising body	Norfolk Public Health, Norfolk County Council
1.2 Description of medicine	Nicotine Replacement Therapy (NRT)
1.3 Legal classification	GSL (General Sales List) and P (Pharmacy)
1.4 Clients	Clients who smoke and are receiving support from a Stop Smoking Advisor commissioned by Public Health Norfolk.
1.5 Professionals involved in supply under the direction	<p><u>Smoking Cessation Advisor (issue voucher):</u> Prior to being able to issue vouchers under this protocol, Stop Smoking Advisors must have completed an Authority approved Level 2 training and have a valid advisor number issued by the commissioned Stop Smoking Service for Norfolk</p> <p><u>Pharmacist (dispense against voucher):</u> To supply NRT under this protocol the Pharmacy must be aware of the NRT formulary (appendix 1) This list is not exhaustive and do not discharge the pharmacist's clinical responsibility for supplying medication. Pharmacies are advised that it is acceptable to receive NRT vouchers through fax (in line with the safe haven faxing policy) from the specialist stop smoking service.</p>
1.6 Supply outside the Summary of Product Characteristics (SPC)	Products must not be supplied outside of the Summary of Product Characteristics (SPCs) (https://www.medicines.org.uk/emc/browse-documents)
1.7 Period	1 st April 2017 to 1 st April 2019

2. Clinical Condition / Indication

2.1 Indication / definition of condition	Tobacco dependence,
2.2 Criteria for inclusion	Tobacco users receiving support from a Smoking Cessation Advisor who provides Stop Smoking Services as commissioned by Public Health Norfolk.
2.3 Criteria for exclusion	<ul style="list-style-type: none"> • Clients not receiving support from a Stop Smoking Advisor <p>Clients receiving support from a Stop Smoking Advisor and also:</p> <ul style="list-style-type: none"> • Have experienced an acute cardio-vascular event within the last 4 weeks without a written recommendation from the consultant for NRT treatment • Clients with previous serious adverse reaction to NRT or any of the other ingredients contained in the products.

	<ul style="list-style-type: none"> • [Patches only] clients with any skin disorders or broken skin. Clients who have had a previous reaction to transdermal patches. • [Nasal spray only] clients with chronic nasal disorders such as polyposis, vasomotor rhinitis and perennial rhinitis. • [QuickMist and Oral Strips only] Patients undergoing treatment for alcohol dependency (Advisory due to alcohol content) • Clients under the age of 12 unless under the supervision of a level 3 advisor.
2.4 Criteria for seeking advice from the Clinical lead or referring to a GP	<p>When the following criteria apply, further advice should be sought in the first instance from the clinical lead for the Stop Smoking Provider and if necessary the clinical lead should liaise with the client's GP if deemed necessary. (Could this include Level 3 (issuing voucher) or Pharmacist?</p> <ul style="list-style-type: none"> • There is doubt about whether an exclusion criteria applies • Clients taking: Theophylline, Aminophylline, Adenosine, Clozapine, Warfarin. • Clients who have experienced an acute cardiovascular event within the last 4 weeks • Clients with diabetes when initiating treatment • Clients with active peptic ulcer disease • Clients with a moderate or severe hepatic impairment • Clients with severe renal impairment • Clients with oesophagitis • Clients with a persistent cough or breathlessness • Clients who are pregnant • Clients who are between 12-18 years old

3. Treatment

3.1 Name of medicine	Nicotine Replacement Therapy
3.2 Form, Administration and Dosage	See Appendix 1 for individual product details
3.3 Length of treatment and supply quantity	<p>NRT may be issued via an NRT voucher:</p> <ul style="list-style-type: none"> • For a maximum of 12 weeks in total. • For a maximum of 2 weeks per voucher issued. <p>No more than 2 NRT products may be given on one voucher or at any one time. (See section 3.9)</p>

3.4 Drug interactions

Smoking cessation, with or without NRT may alter the effects of certain other medications) which may require dose adjustment. These are listed below:

- Adrenergic agonists and antagonists
- Antihypertensive drugs
- Benzodiazepines
- Chlorpromazine
- Clomipramine
- Clozapine
- Duloxetine
- Flecainide
- Fluphenazine
- Fluvoxamine
- Haloperidol
- Imipramine
- Insulin
- Lithium
- Memantine
- Olanzapine
- Pentazocine
- Propranolol
- Ropinirole
- Tacrine
- Tricyclic antidepressants
- Warfarin
- Zolpidem
-

If the client is diabetic, breathless, has a persistent cough or is taking one of the medicines listed below, the professional supplying NRT shall **notify the client's GP or an appropriate healthcare professional** and discuss this with the patient:

- **Theophylline and Aminophylline** - *Tobacco smoking increases the metabolism of theophylline. Thus stopping smoking may cause theophylline plasma levels to rise. Clients taking theophylline should be supplied with NRT as appropriate but the professional shall inform their GP of their attempt to quit.*
- **Adenosine** - *NRT can have an adverse haemodynamic effect. If a client is using Adenosine, advice must be sought from the client's GP or consultant prior to supplying NRT.*
- **Clozapine** - *Tobacco smoking increases the metabolism of clozapine. Smoking cessation can cause the blood level of clozapine to rise. For clients using Clozapine, the client's Community Psychiatric Nurse or GP must be informed of the client's attempt to stop smoking in order for them to decide if they*

	<p><i>wish to monitor the client's blood levels as appropriate.</i></p> <ul style="list-style-type: none"> • Warfarin • Insulin/Diabetes: Clients who have diabetes and/or are using Insulin should be advised to monitor their blood sugar levels regularly whilst stopping smoking. <p>Permission to pass this information to the GP will need to be obtained from the client. (? Check re PharmOutcomes template re supply if no GP permission)</p>
<p>3.5 Side effects / adverse reactions</p>	<p>Side effects from NRT and/or the consequence of stopping smoking are usually transient but may include some of the list below:</p> <ul style="list-style-type: none"> • nausea • dizziness • headaches • cold and flu-like symptoms • palpitations • dyspepsia and other gastro-intestinal disturbances • increased appetite • flatulence • insomnia • vivid dreams • myalgia • chest pain • blood pressure changes • anxiety and irritability • somnolence and impaired concentration • dysmenorrhoea <p>Product-specific side effects are detailed in the Summary of Product Characteristics.</p>
<p>3.6 Advice to clients</p>	<p>Advice to clients on dispensing NRT should include specific product advice plus the following general advice on:</p> <ul style="list-style-type: none"> • withdrawal symptoms • possible changes in the body on stopping smoking, e.g. weight gain • possible side effects • the effects of smoking tobacco whilst using NRT • written information on NRT products supplied, self-help leaflets and where to obtain more information

3.7 Providing NRT products to Clients	<p>All NRT must be given to the client that is receiving the support.</p> <p>The Pharmacist supplying NRT should ask the following questions:</p> <ul style="list-style-type: none"> • Is the client taking any other medications? • Does the client suffer from any medical conditions? • Has the client been advised how to use the products?
3.8 Exemption from prescription charges	<p>The pharmacy supplying NRT must ask clients who are exempt from prescription charges for evidence of that exemption.</p> <p>It may be appropriate to recommend the purchase of a prepayment certificate.</p> <p>Reason for exemption will be captured on the data management system.</p> <p>Where a patient is not exempt from prescription charges the pharmacy must collect such charges and this sum deducted from the remuneration due to the pharmacy.</p>
3.9 Combination Therapy Guidance	<p>Clients should be advised to try a single product before trying combination therapy unless client has experience of NRT usage and a single product does not satisfy withdrawal needs.</p> <p>When dispensing combination therapy a maximum of two products may be used. It is recommended that one product is in the form of NRT patches and quantities of the second NRT product takes into account that a baseline dose is being given via patch.</p> <p>Other combination Therapy may be considered only under the guidance of a Level 3 advisor.</p>
3.10 Giving clients choice	<p>Clients must be given a choice of NRT products and decide with the Stop Smoking Provider/Advisor which product(s) is best for them</p> <p>See appendix 1 for a list of approved NRT products</p>
3.11 Pregnant and Breast feeding women	<p>The data available on the use of NRT in pregnancy and breast feeding women is limited, however, the dangers of continuing to smoke are well established and are likely to be considerably more damaging to mother and baby than any potential risk of NRT. In light of this, The Expert Committee on Safety of Medicine Working Group advised that pregnant women, who cannot stop smoking on their own, can use NRT, as can breast feeding women.</p> <p>Pregnant women should avoid use of 24 hour patches or remove them at night.</p>

3.12 Clinical pathway

Issuing Vouchers for Nicotine Replacement Therapy under this protocol should only take place as part of the delivery of a full Stop Smoking Service delivered by an advisor who is contracted to deliver stop smoking services by Public Health Norfolk.

Supply of NRT on recommendation of a Level 3 Stop Smoking Advisor should only take place in pharmacies contracted to deliver all or part of the Stop Smoking Primary Care Contract commissioned by Public Health Norfolk.

4. Authorisation

This protocol has been authorised by the following professionals on behalf of the commissioning organisation (Norfolk County Council):

Name	Designation	Organisation	Signature	Date
Dr Augustine Pereira	CPHM	Public Health Norfolk		5 th June 2014
Angela Fletton	PHCM	Public Health Norfolk		
Sue Marshall	Clinical Governance Manager	Public Health Norfolk		
Alice Vickers	PHO	Public Health Norfolk		

The protocol has been endorsed by the following professionals:

- Tony Dean Chief Officer, Norfolk Local Pharmaceutical Committee.
- Fotoula Blias, Service Manager for Specialist Therapies, Norfolk Community Health and Care NHS Trust
- Linda Robinson, Stop Smoking Service Lead (Clinical Lead) East Coast Community Healthcare CIC

In addition, North and East London CSU Medicines Management was consulted in the drawing up of this Protocol.

Nicotine replacement Therapy Formulary

Approved NRT products and pack sizes

(Products licensed after the issuing of this protocol may be considered –please check before using)

Product	Strength	Approved Pack sizes
Nicorette Chewing Gum (all flavours)	2mg	30, 105
Nicorette Chewing Gum (all flavours)	4mg	30, 105
Nicorette Inhalator	15mg	20, 36
Nicorette invisipatch	10mg	7
Nicorette invisipatch	15mg	7
Nicorette invisipatch	25mg	7, 14

Nicorette Microtab	2mg	30, 100
Nicorette Nasal spray (not Quickmist)	0.5mg/50iu	10ml
Nicorette Quickmist Nasal Spray	1mg	13.2ml, Twinpack (2x13.2ml)
Nicotinell gum	2mg	24, 72, 96, 204
Nicotinell gum	4mg	24, 72, 96
Nicotinell lozenge	1mg	36, 96
Nicotinell lozenge	2mg	36, 72, 96, 144
Nicotinell patch TTS 10	7mg	7
Nicotinell patch TTS 20	14mg	7
Nicotinell patch TTS 30	21mg	7, 21
Niquitin Gum	2mg	12,24, 96
Niquitin Gum	4mg	12, 24, 96
Niquitin Lozenge	2mg	36, 72
Niquitin Lozenge	4mg	36, 72
Niquitin Minis (all flavours)	1.5mg	20, 60
Niquitin Minis (all flavours)	4mg	20, 60
Niquitin Patch (original & clear)	7mg	7
Niquitin Patch (original & clear)	14mg	7
Niquitin Patch (original & clear)	21mg	7,14
Niquitin Strips (Mint)	2.5mg	15, 60
Nicorette Chewing Gum (all flavours)	2mg	25, 30, 105, 210

All products should be supplied in line with the latest Summary Product Characteristics (SPCs).