

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

Document Control

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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 County Council, Public Health (NCCPH)
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 trained Stop Smoking Advisor commissioned by NCCPH.
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. Vouchers will be supplied via an electronic database or PharmOutcomes.</p>
1.6 Supply outside the Summary of	Products must not be supplied outside of the Summary of Product Characteristics (SPC)

Product Characteristics (SPC)	(https://www.medicines.org.uk/emc/browse-documents)
1.7 Period	22 nd September 2023 to 22 nd September 2025

2. Clinical Condition / Indication

2.1 Indication / definition of condition	Tobacco dependence
2.2 Criteria for inclusion	Tobacco users identified as sufficiently motivated to quit are receiving support from a Smoking Cessation Advisor who provides Stop Smoking Services, as commissioned by Norfolk County Council Public Health.
2.3 Criteria for exclusion	<ul style="list-style-type: none"> • Clients not receiving support from a Stop Smoking Advisor • Tobacco users not sufficiently motivated to quit or use NRT. <p>Clients receiving support from a Stop Smoking Advisor and:</p> <p>have experienced an acute cardio-vascular event within the last 4 weeks without a written recommendation from the consultant for NRT treatment.</p> <ul style="list-style-type: none"> • Clients with previous serious adverse reaction to NRT or any of the other ingredients contained in the products. • [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 Health Care Provider including any secondary care specialist.</p> <ul style="list-style-type: none"> • There is doubt about whether an exclusion criteria applies • Clients who are prescribed: Theophylline, Aminophylline,

	<p>Adenosine, Clozapine, Warfarin.</p> <ul style="list-style-type: none"> • Clients who have experienced an acute cardio-vascular event within the last 4 weeks. • Clients with diabetes at the point of initiation of NRT treatment. • Clients with active peptic ulcer disease • Clients with 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 12-17 years old
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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 National Guidance and resources on NRT Supply	<ul style="list-style-type: none"> • NICE – Nicotine replacement therapy (NRT) Prescribing information Smoking cessation CKS NICE • Recommendations on promoting quitting Tobacco: preventing uptake, promoting quitting and treating dependence Guidance NICE • NCSTC - Stop smoking medications (ncsct.co.uk) • EMC - Home - electronic medicines compendium (emc) • Nicotine Drugs BNF NICE <p>The above guidance and resources should be used to inform the prescribing and supply of NRT to clients, which outline the licensed NRT products, SPCs, drugs affected by NRT, contraindications, adverse effects, and dosing and duration</p>
3.4 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>
3.5 Drug interactions	

There are no known clinically relevant drug- drug interactions with NRT. However, acidic beverages, such as coffee or fruit juice, may decrease the absorption of oral nicotine and should be avoided for 15 minutes before the use of oral NRT.

There are several known clinically significant drug interactions with tobacco smoking. Therefore, smoking cessation with or without the use of NRT, or the restarting of smoking after a period of cessation, may alter the effects of certain medications. This may result in doses of prescribed medications needing to be adjusted to ensure they remain at a safe dose for the client. Most interactions are due to a component of tobacco smoke and not due to nicotine, so these interactions are not expected to occur with NRT or e-cigarettes (vapes).

The most clinically important interactions are listed below. If the affected drug is prescribed under the supervision of a specialist, they should be notified if the client changes their smoking status. For further information regarding the interactions below, please consult the relevant SPC.

High clinical relevance – the effects of smoking cessation is usually seen within one week so a relevant health professional involved in the client's care must be notified at the earliest opportunity to allow for appropriate monitoring and any necessary dose adjustments. If a client wishes to restart smoking and is prescribed any of the below medications, the health professionals involved in their care must be informed of the change in smoking status.

Theophylline and Aminophylline – Tobacco smoking can increase blood levels of theophylline and aminophylline. Stopping smoking may cause theophylline plasma levels to rise and therefore a dose reduction may be required. If a client starts to smoke again, their dose of theophylline or aminophylline may need to be increased as smokers often need a higher dose.

Clients taking theophylline should be supplied with NRT as appropriate, but the professional must inform their GP of the client's attempt to quit as soon as possible.

Clozapine – This is a high-risk drug and blood level monitoring must be undertaken before any attempt to stop smoking and one week after smoking cessation. Tobacco smoking increases the metabolism of clozapine therefore smoking cessation can cause the blood level of clozapine to rise. For clients using Clozapine, their Community Psychiatric Nurse and GP must be informed of the client's attempt to stop smoking. This must be supported by Mental Health Services who are clinically responsible for this medication.

If a client who has previously stopped smoking wishes to re-start, blood monitoring is required prior to restarting smoking. The Community Psychiatric Nurse, GP and Mental Health Services must be made aware so dose adjustments can be made.

Erlotinib – Tobacco smoking can reduce the effectiveness of Erlotinib and therefore gain less clinical effect than non-smokers. Current smokers should be advised to stop smoking as early as possible before initiation of erlotinib treatment.

Olanzapine – Tobacco smoke affects the metabolism of olanzapine. Smoking increases the clearance of olanzapine and therefore smokers have lower olanzapine blood levels. As a result, smokers often require higher daily doses compared to non-smokers. Upon smoking cessation, doses may need to be reduced or increased if smoking is restarted. The effects are seen with both oral and prolonged-release injections (depot).

Riociguat – Blood levels of riociguat are reduced in smokers compared to non-smokers and therefore smokers may require higher doses. A dose decrease may be required in clients who wish to stop smoking. This drug should only be prescribed by specialist; they should

always be advised if a client wishes to stop (or restart) smoking to review any dose adjustments.

Moderate risk

The following drugs are classed as having a moderate risk interaction with tobacco smoke. The clients GP and/or specialist must be notified if the client wishes to stop or start smoking after previous cessation.

- Chlorpromazine
- Flecainide
- Methadone
- Ropinirole
- Warfarin – the client must be made aware that there may be a need for closer INR monitoring on smoking cessation and warfarin doses may need adjusting accordingly.

Other less clinically significantly drug-smoking interactions include (not exhaustive):

- Antidepressants
 - SNRIs – particularly duloxetine
 - SSRIs – particularly fluvoxamine
 - Tricyclics – particularly clomipramine and Imipramine
- Antihypertensives
 - ACE inhibitors
 - Beta-blockers
 - Calcium channel blockers
- Antiplatelets – in particular clopidogrel
- Antipsychotics – (in addition to those listed above) including Fluphenazine and haloperidol
- Benzodiazepines
- Corticosteroids (inhaled only)
- Insulin - Clients who have diabetes and/or are using insulin should be advised to monitor their blood sugar levels regularly whilst stopping smoking.
- Opioids

Permission to pass this information to the GP or other relevant HCP will need to be obtained from the client. It is advisable for these drugs that this contact is made/ advice obtained prior to any stop in smoking or intervention is agreed.

References:

Relevant SPCs [Home - electronic medicines compendium \(emc\)](#)

SPS – Interactions with tobacco: 2020. https://www.sps.nhs.uk/wp-content/uploads/2020/03/UKMi_QA_Interactions-with-tobacco_update_Jul-2020.pdf

CKS – Smoking cessation; which drugs are affected by stopping smoking? April 2023

3.6 Side effects / adverse reactions

Side effects from NRT and/or the consequence of stopping smoking are usually transient but may include some of the list below:

- nausea
- dizziness
- headaches

	<ul style="list-style-type: none"> • 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 • dysmenorrhea <p>Product-specific side effects are detailed in the Summary of Product Characteristics.</p>
3.7 Advice to clients	<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 which should be related to the chosen NRT product. • the effects of smoking tobacco whilst using NRT • written information on NRT products supplied, self-help leaflets and where to obtain more information. • Clients experiencing common side effects should be offered symptomatic advice and encouraged to persevere with treatment/cessation. <p>Clients experiencing uncommon/ rare very rare side effects should be advised to stop treatment and to see their GP for further advice.</p>
3.8 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 including those prescribed by any healthcare professional, specialist or purchased.? • Does the client suffer from any medical conditions? • Has the client been advised how to use the products?

3.9 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>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> <p>It may be appropriate to recommend the purchase of a prepayment certificate.</p>
3.10 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>
3.11 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>
3.12 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. Considering 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>
3.13 Clinical pathway	<p>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 Norfolk County Council Public Health.</p>

	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 Norfolk County Council Public Health.
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4. Authorisation

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

In addition, the ICB Medicines Optimisation Team was consulted in the drawing up of this Protocol.

Name	Designation	Organisation	Date
Marion Sulley	Project Lead Pharmacist Medicines Optimisation	ICB	30/08/23
Hayley Hurst	Medicines Optimisation Pharmacist	ICB	30/08/23
Suzanne Wilkin	APHO	NCCPH	30/08/23
Hannah Clarke	APHO	NCCPH	30/08/23
Sue Marshall	Safeguarding Manager/Reducing Drug and Alcohol Related Deaths Coordinator	NCCPH	30/08/23
Lauren Seamons	Norfolk Local Pharmaceutical Committee	LPC	22/09/2023

Appendix 1 – 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)

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

Please also note that advisors should be aware of the product costs and aim to provide products which balance value with patient choice. On PharmOutcomes, up to date tariff prices are automatically displayed to facilitate this consideration and can be used in compliment to the below.

First Choice

Second Choice

Third choice

Product	Strength	Approved pack sizes	£
Nicorette Chewing Gum (all flavours)	2mg	30, 105	£4.80
			£11.89
Nicorette Chewing Gum (all flavours)	4mg	30, 105	N/A
			£14.55
Nicorette Inhalator	15mg	20, 36	£22.64
			£35.66
Nicorette invisipatch	10mg	7	£11.43
Nicorette invisipatch	15mg	7	£11.43
Nicorette invisipatch	25mg	7, 14	£11.43
			£18.72

Nicorette Microtab	2mg	30, 100	N/A
			£19.14
Nicorette Nasal spray (not Quickmist)	0.5mg/50iu	10ml	£21.05
Nicorette Quickmist Nasal Spray	1mg	13.2ml, Twinpack (2x13.2ml)	£23.29
Nicotinell gum	2mg	24, 72, 96, 204	N/A
			N/A
			£9.50
			£18.00
Nicotinell gum	4mg	24, 72, 96	N/A
			N/A
			£11.79
Nicotinell lozenge	2mg	36, 72, 96, 144	N/A
			N/A
			£12.19
			£15.53
Nicotinell Lozenge	4mg	36,72	N/A
			N/A
Nicotinell patch TTS 10	7mg	7	£9.12

Nicotinell patch TTS 20	14mg	7	£9.40
Nicotinell patch TTS 30	21mg	7, 21	£9.97
			£24.51
Niquitin Gum	2mg	12,24, 96	N/A
			N/A
			N/A
Niquitin Gum	4mg	12, 24, 96	N/A
			N/A
			N/A
Niquitin Lozenge	2mg	36, 72	N/A
			£7.40
Niquitin Lozenge	4mg	36, 72	N/A
			£7.40
Niquitin Minis (all flavours)	1.5mg	20, 60	N/A
			£12.56
Niquitin Minis (all flavours)	4mg	20, 60	N/A
			£12.56
Niquitin Patch (original & clear)	7mg	7	£11.48
Niquitin Patch (original & clear)	14mg	7	£11.48

Niquitin Patch (original & clear)	21mg	7,14	£11.48
			£18.79
Niquitin Strips (Mint)	2.5mg	15, 60	N/A
Nicorette Chewing Gum (all flavours)	2mg	25, 30, 105, 210	N/A
			£4.80
			£11.89
			£19.34