

The Medical Management of Tobacco Dependency

January 2022

Review due in January 2025

Document Control

Revision History:

The latest version will be held on the GMMMG website.

Date	Actioned by	Comments/Summary of changes	Version
2019	Tobacco Addiction Treatment working group (Matt Evison ¹ , Murugesan Raja ² , Lara Shah ³)	Production of new guidance	V0.1
April 2020	Andrew Martin ⁴	Minor amendments after Formulary and Managed Entry Subgroup 25.02.20	V0.2
June 2021	Clinical Advisory Group for Tobacco Addiction Treatment (Murugesan Raja)	Amendments to align with draft 2021 NICE guidance	V0.3
January 2022	Andrew Martin, Matt Evison	Minor amendments to align with finalised NICE 2021 guidance	V0.4
January 2022	Andrew Martin, Matt Evison, Murugesan Raja	Further minor amendments after Medicines and Guidelines Subgroup. Formatting changes	V1.0

Approval:

This document must be approved by the following before distribution:

Name	Title	Date of Approval	Version
GMMMG (MGSG)	Tobacco Dependency Treatment Guideline	24 th January 2022	V1.0

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Greater Manchester Tobacco Dependency Treatment Guideline

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Adults (see separate guidance that follows this for Young people 12-17 and Pregnant Women)

Step 1: Offer all patients that smoke, brief advice (*in line with NCSCCT standards*)

Step 2: Offer referral to a specialist stop smoking service **PLUS** offer pharmacotherapy/advice on evidenced based interventions in line with this protocol. **Smokers are three times more likely to quit with the help of BOTH medications and specialist support.** However, if a patient declines a referral to a stop smoking service this **should not preclude the provision of pharmacotherapy (NICE 2018, 2021)**

Patients should be informed about all the available options so they can make an informed choice. However, if they would like to understand which interventions are the most effective this protocol can help guide healthcare professionals in providing this information. Interventions below can be used in combination at the discretion of the healthcare professional on a case-by-case basis (NICE 2021).

Very effective: varenicline* (up to 12 weeks, not in pregnancy)

- 0.5mg once daily Day 1-3
- 0.5mg *twice* daily Day 4-7
- 1mg twice daily Day 8+
- *Reduce smoking and set quit date in 1-2 weeks if possible*

Evidence Base for this recommendation:

- ✓ In a NICE technology appraisal Varenicline was demonstrated to be superior to NRT and bupropion in achieving continuous abstinence. Over a lifetime horizon varenicline dominated bupropion and NRT – it was cheaper and more effective in all sensitivity analysis.
- ✓ Varenicline was more effective in achieving short-term and long-term abstinence in a head to head randomized controlled trial in patients both with and without mental health illness in comparison to placebo, NRT and bupropion (EAGLES Study, The Lancet 2016)
- ✓ A Cochrane review reported the number needed to treat with varenicline to achieve an additional long-term quitter versus placebo was 11, compared to 22 and 23 for bupropion and NRT respectively (Cahill. *Cochrane Database Syst Rev* 2016)

Consider extending varenicline to 24 weeks in the following scenarios:

- ✓ Patient was smoking beyond the first six weeks of treatment
- ✓ ≥2 quit attempts in the previous 12 months
- ✓ Previous successful 12 weeks treatment but subsequent relapse

Take with food and water to help avoid nausea. Warn of sleep disturbance and vivid dreams. Consider reducing to 0.5mg BD if intolerable side effects

*** At the time of production of this guideline, varenicline was unavailable. The next most effective pharmacotherapy is combined NRT (next page).**

Effective: Combination Nicotine Replacement Therapy (NRT):

Patients will naturally wean dose as able but to be supplied for as long as is needed to prevent relapse (NICE 2021)

Prescribe or provide a high dose nicotine patch

- **21mg / 24hrs** (preferred if craving to smoke is significant from moment of waking – e.g. within 30 minutes)
- **25mg / 16hrs** (preferred if 24hr patch causes sleep disturbance or concerns over sleep disturbance)

Prescribe or provide high dose short acting nicotine

- **Nicotine gum/lozenge: 4mg prn**
- **Nicotine microtab: 4mg prn**
- **Nicotine nasal spray: up to 4 sprays both nostrils prn (0.5mg/spray)**
- **Nicotine mouth spray: 4mg prn (1mg/spray)**
- **Nicotine inhalator: use as much as needed**

Agree a quit date and ensure the person has NRT ready to start the day before the quit date

Evidence Base for this recommendation:

- ✓ Cochrane review (63 trials, 41,509 participants) Combination NRT (fast-acting form + patch) results in higher long-term quit rates than single form (RR 1.25, 95% CI 1.15 to 1.36, 14 studies, 11,356 participants)
- ✓ 21 mg patches more effective than 14 mg (24-hour) patches (RR 1.48, 95% CI 1.06 to 2.08, one study, 537 participants).
- ✓ 25 mg patches more effective than 15 mg (16-hour) patches (RR 1.19, 95% CI 1.00 to 1.41, three studies, 3,446 participants)
- ✓ 4 mg gum more effective than 2 mg gum (RR 1.43, 95% CI 1.12 to 1.83, five studies, 856 participants)

Encourage patients to use the short acting nicotine regularly e.g. on the hour every hour.

Cravings for nicotine are extremely powerful and NRT is weaker than cigarettes. Patients cannot overdose on nicotine except for causing mild symptoms such as light-headiness or nausea. However, under-dosing will affect how well NRT can alleviate cravings!

Please note that NRT prescribing in pregnancy differs to this pathway – see separate guidance on page 9.

Very effective: Vaping/Nicotine-containing Electronic Cigarettes

Nicotine-containing electronic cigarettes are a form of nicotine replacement that utilise a vapour of nicotine within an alcohol-based solvent and facilitates alveolar absorption of nicotine mimicking tobacco smoke (unlike other forms of NRT). E-cigarettes provide higher levels of blood nicotine than other forms of NRT.

- Vaping / use of e cigarettes is likely to be substantially less harmful than smoking (NICE 2021; 95% less harmful – PHE)
- There is not enough evidence to know whether there are long-term harms from e-cigarette use
- Advise patients choosing to vape to switch entirely to using e-cigarettes and stop smoking tobacco completely
- This is dependent upon getting enough nicotine to overcome withdrawal symptoms – advise patients to use the strongest nicotine strength liquid (18mg) and to use the electronic cigarette as much as is required to prevent relapse to smoking

Evidence Base for this recommendation:

- ✓ In a 900 patient UK RCT of NRT (patient choice) for up to 3 months vs an e-cigarette starter pack (a second-generation refillable e-cigarette with one bottle of 18 mg/L nicotine) plus at least 4 weeks of behavioural support for all participants the 12 month abstinence rate was 9% vs 18% respectively (Hajek. NEJM 2019).
- ✓ Cochrane Review of 50 studies (26 RCTs, 12,430 participants) concluded there was moderate-certainty evidence that quit rates were higher in people randomized to nicotine EC than in those randomized to nicotine replacement therapy (RR 1.69). In absolute terms, this might translate to an additional four successful quitters per 100. (Hartmann-Boyce. Cochrane Tobacco Addiction Group 2020)

Advise devices & liquids are purchased from licensed vendors regulated under UK law. Do not use oil-based solvent liquids.

Be vigilant for any suspected adverse reactions associated with use of e-cigarettes or vaping (including lung injury) and report them to the MHRA via the Yellow Card Scheme.

Greater Manchester supports the provision of vaping kits as part of tobacco dependency treatment offers and the commissioning of services to include this offer.

Selling or supply of E-Cigarettes/Vaping devices is illegal in persons under 18 years of age.

Pharmacotherapy interventions that have demonstrated efficacy for smoking cessation versus placebo but are considered less effective than the interventions described above are:

- Bupropion
- Single NRT – short acting
- Single NRT – long acting

Bupropion (*Ensure medication review & assessment of seizure risk completed*)

- The initial dose is 150mg to be taken daily for six days, increasing on day seven to 150mg twice daily.
- Bupropion treatment course is 7-9 weeks.
- There should be an 8 hour gap between doses of bupropion (insomnia is a common side effect which can be reduced by avoiding doses at bedtime provided there is at least 8 hours between doses.
- *Agree a quit date set within the first 2 weeks of treatment, reassess the person shortly before the prescription ends*

Reduce dose to 150mg OD in the elderly, renal impairment, hepatic impairment or any of the following medications: anti-psychotics, anti-depressants, anti-malarials, tramadol, theophylline, corticosteroids, quinolones, anti-histamines.

Due to seizure risk avoid in patients with the potential for lowered seizure threshold e.g. alcohol abuse, diabetes with hypoglycaemic episodes, head trauma. Due to mania risk avoid in bipolar disease. Avoid prescription with tamoxifen (reduces serum levels)

Stopping smoking and mental health illness

Smoking prevalence is significantly higher in those with mental health illness (40-50%) and stopping smoking is one of the best treatments for mental health disease with an effect larger than anti-depressants (BMJ 2014). Stop smoking medications are highly effective in patients with mental health disease (RCPsych) and significant benefit could be made by increasing access to these medications (ASH).

There is no increased risk of moderate to severe neuropsychiatric adverse events with varenicline, NRT or bupropion (EAGLES study 2016, The Lancet). The act of stopping smoking carries a small risk of moderate to severe neuropsychiatric events and this is regardless of the treatment used. The risk is higher in those with a history of psychiatric illness (5%) versus those without (2%). **Advise patients to seek help in the event of a neuropsychiatric event. Mental health illness is not a contraindication to prescribing stop smoking pharmacotherapy.**

Young people 12-17 years of age

Step 1: Offer all smokers brief advice (*in line with NCSCCT standards*)

Step 2: Offer all smokers a referral to a specialist stop smoking service and use professional judgement when deciding whether to offer NRT to young people who are dependent on nicotine. Do not prescribe varenicline or bupropion to people aged under 18 years old.

Nicotine Replacement Therapy

Selling or supply of E-Cigarettes/Vaping devices are illegal in children and in this age group.

There is limited evidence which suggests that there is no specific intervention (including pharmacotherapy) that is more successful than stopping unaided in the adolescent population.

A combination of long-acting and short-acting NRT may be beneficial for young people >12 years if they have a high level of nicotine dependence or in those who have failed on previous NRT treatment. *All preparations are licensed for children over 12 years with the exception of Nicotinell® lozenges which are licensed for children less than 18 years only when recommended by a doctor.*

Prescribing NRT in children and young people should be in line with the licensing of the medicine and as per [cBNF](#).

A quit date should be agreed when NRT is prescribed, and treatment should be available before the child stops smoking. Young people should be prescribed enough treatment to last 2 weeks after their agreed quit date and be re-assessed shortly before the prescription ends.

Pregnancy

Step 1: Identify pregnant smokers, offer brief advice (*in line with Greater Manchester Smokefree Pregnancy programme standards*) and, if they wish, refer immediately to their specialist stop smoking midwifery team to receive evidence-based stop smoking support.

Step 2: Prescribe Nicotine Replacement Therapy (NRT) as a safe alternative to smoking until the first appointment with the midwife. Do not prescribe varenicline or bupropion to pregnant or breastfeeding women.

There is strong evidence that smoking or being exposed to second-hand smoke during pregnancy increases the risk of miscarriage, certain birth defects, premature birth, poor growth of the baby and increased risk of stillbirth, exposure has also been directly linked to health problems later on in life.

Nicotine Replacement Therapy

NRT is an effective stop smoking aid and is licensed for use in pregnancy. Although studies have not been able to demonstrate its effectiveness in isolation, primarily due to problems with compliance, NICE supports use of NRT in pregnancy in conjunction with behavioural support to help women quit and stay smoke free.

Consider the following:

- Pregnant smokers metabolise nicotine faster than other smokers so NRT may be required to manage nicotine withdrawal. Intermittent therapy is preferable to patches - avoid liquorice-flavoured nicotine products as manufacturers advise caution due to potential for adverse effects associated with excessive amounts of liquorice root. As other flavours are available, pregnant women are advised to choose an alternative, such as fruit or mint.
- Patches are useful in the presence of pregnancy-related nausea and vomiting – however 24-hour patches should be avoided or removed before bed.
- Prescribe NRT to manage nicotine withdrawal until the first appointment with the midwife and prior to commencing the Smokefree Pregnancy pathway.
- Do not offer varenicline or bupropion.

Vaping

Vaping is a form of nicotine replacement that utilise a vapour of nicotine within an alcohol-based solvent and facilitates alveolar absorption of nicotine mimicking tobacco smoke (and unlike other forms of NRT). Pregnant smokers metabolise nicotine faster than other smokers and may need higher doses of nicotine. Vaping provide higher levels of blood nicotine than other forms of NRT. In an RCT of NRT vs e-cigarettes (vaping) the 12-month abstinence rate was 9% vs 18% respectively (NEJM 2019). Although nicotine from vaping crosses the placenta it does not contain other toxic ingredients found in cigarette smoke. The Royal College of Midwives recommends that pregnant smokers choosing to use vaping as an aid to smoking cessation should be supported to do so and offered referral to the midwifery team where they will be supported by the specialist stop smoking midwife.

Advise devices & liquids are purchased from licensed vendors regulated under UK law. Do not use oil-based solvent liquids.

Additional information

The Smokefree Pregnancy programme is an evidence-based programme across Greater Manchester, providing a standardised Smokefree Pregnancy pathway and enabling those who are pregnant and their partners to protect their babies through pregnancy and beyond.

The programme aims to deliver quit rates above the national average and ultimately for no person to smoke during their pregnancy.