Essex Partnership University
NHS Foundation Trust

SECTION 17: SMOKING CESSATION THERAPY

Formulary and Prescribing Guidelines

17.1 Introduction

These guidelines should be used in conjunction with EPUT 'Smokefree Policy' (CPG32) for service users who are 12 years old and over.

The following is advised [1-4]:

Nicotine replacement therapy (NRT), varenicline and cytisinicline (nicotinic receptor agonists), and bupropion hydrochloride (a selective dopamine and noradrenaline reuptake inhibitor), are effective drug treatments to aid smoking cessation and should be offered alongside behavioural support. The choice of drug treatment should take into consideration the individual's likely adherence, preferences, and previous experience of smoking-cessation aids, as well as contra-indications and side-effects of each preparation. Varenicline, cytisinicline or a combination of long-acting NRT (transdermal patch) and short-acting NRT (lozenges, gum, sublingual tablets, inhalator, nasal spray and oral spray), are the most effective treatment options and thus the preferred choices. If these options are not appropriate, bupropion hydrochloride or single therapy NRT should be considered instead.

Nicotine transdermal patches are generally applied for 16 hours, with the patch removed overnight; if individuals experience strong nicotine cravings upon waking, the patch can be applied for 24 hours (kept on while sleeping) instead. Short-acting nicotine preparations are used whenever the urge to smoke occurs or to prevent cravings; there is no evidence that one form of NRT is more effective than another.

The use of NRT combined with non-nicotine smoking cessation therapy (varenicline, cytisinicline or bupropion hydrochloride) is not recommended, and the non-nicotine smoking cessation therapy options (varenicline, cytisinicline and bupropion hydrochloride) should not be prescribed together.

A quit date should be agreed when smoking cessation therapy is prescribed, and treatment should be available before the individual stops smoking. For those who have successfully stopped smoking, offer the opportunity for a further course of varenicline, NRT, or bupropion hydrochloride [unlicensed] to prevent a relapse to smoking. Please note that a further course of cytisinicline should not be offered until after 2-3 months from initial trial.

Individuals who are unwilling or not ready to stop smoking may also benefit from the use of NRT as part of a 'harm reduction approach', because the amount of nicotine in NRT is much lower and the way these products deliver nicotine makes them less addictive than smoking tobacco. These individuals should be advised that NRT will make it easier to reduce how much they smoke and improve their chance of stopping smoking in the long-term. NRT can be used for as long as needed to help prevent a return to previous levels of smoking. All inpatients should be encouraged to stop smoking as part of their Care Programme Approach (CPA). Smoking Cessation Advisers are available to offer support to service users.

A meta-analysis (Taylor et al 2014)[5] has concluded that contrary to previous beliefs stopping smoking has been shown to improve mental state.

All Licensed smoking cessation therapy for use by inpatients must be prescribed by a doctor (or a non-medical prescriber) and stored with other medicines. Service users should not store their own smoking cessation medication/products.

Product, dosage and frequency will be determined by the MDT and strict parameters (such as the duration of treatment) included in the care plan. The length of time a patient has been

smoking and the number of cigarettes/e-cigarettes smoked each day will need to be taken into consideration. Community patients can access 'stop smoking services' via their GP or community pharmacy. Users of E-cigarettes or vaping devices wishing to remain abstinent should be provided with the same level of support and interventions as tobacco smokers wishing to quit. Provide information on how people who smoke can reduce the risk of illness and death (to themselves and others) by using one or more medicinally licensed nicotine-containing products. Explain that they could be used as a partial or complete substitute for tobacco, either temporarily or in the long term.

As part of routine clinical practice[6], clinicians are advised to document use of e-cigarettes or vaping devices in medical records for all patients as they would with smoking. Clinicians should routinely document:

- Name or brand of product used
- Type of product (if known)
- Duration and frequency used
- Substances vaped (for example, nicotine or recreational substances)
- Strengths of substances

Bupropion (Zyban), Varenicline (Champix) and Cytisinicline (Cytisine) should only be offered if the risks have been **fully** assessed and it is felt that the benefits outweigh the risks. A record of the decision must be recorded in the patient's healthcare record.

Bupropion has significant potential to lower seizure thresholds and thus, can interact with many other psychotropic medications[1,2].

Varenicline is strongly associated with the emergence of suicidal thoughts/behaviour and its use in patients with a history of psychiatric illness is only to be undertaken with extreme caution[1,2].

Cytisinicline should not be prescribed to people with unstable angina, recent MI, clinically significant arrhythmias, recent stroke, pregnancy or breastfeeding. It should not be used with anti-tuberculosis drugs. It is thought that cytisinicline may interact with hormonal contraceptives, therefore a second barrier method should be used during treatment[1,2].

Thus, NRT (nicotine replacement therapy) should be the first line pharmacological therapy for smoking cessation offered within EPUT, and the other options (Cytisinicline, varenicline or bupropion) are second line smoking cessation therapy after NRT has been unseuccessful[3]. Behavioural support should be offered alongside smoking cessation therapy for inpatients and consideration given to referring to local 'stop smoking services' in the community at discharge for ongoing behavioural support.

17.2 Precautions

Prescribers should consider that although a service user may not smoke in the inpatient setting, they may do so when on leave or discharged. This may affect plasma levels of their prescribed medicines, which may then need to be adjusted.

Most warnings for NRT also apply to smoking, but the risk of continued smoking outweighs any risk of nicotine preparations. NRT should be used with caution in service users who have cardiovascular disease; peripheral vascular disease; hyperthyroidism;

phaeochromocytoma; diabetes mellitus; renal or hepatic impairment; history of gastritis; peptic ulcers; pregnancy and breast-feeding mothers.

Varenicline should be used with caution in service users with conditions that lower the seizure threshold, those with a history of cardiovascular disease or psychiatric illness and those with a predisposition to seizures. It should be avoided in pregnancy and breast feeding. Dose adjustment is required in renal impairment – see SPC[2].

Cytisinicline should be used with caution in service users with cardiovascular disease, diabetes, gastric and duodenal ulcer, gastro-oesophageal reflux disease, history of psychiatric disease, hyperthyroidism, peripheral vascular disease, phaeochromocytoma and schizophrenia. It is contra-indicated in service users with arrhythmias, recent myocardial infarction, recent stroke and unstable angina. It should be avoided in pregnancy and breast feeding. People able to become pregnant should use highly effective contraception during treatment and additional barrier method as the effect on hormonal contraception is unknown[2].

17.3 Approved NRT Products

Formulation	Dosage[3]	Instructions for use[3]
Nicotine Patch (24hr) 21mg/14mg/7mg	*For individuals smoking 10 or more cigarettes daily, or those smoking less than 10 cigarettes daily, but who have severe withdrawal on 15 mg/day patch*: Apply 21mg/24 hours patch daily. *For individuals smoking less than 10 cigarettes daily*: Apply 14 mg/24 hours patch daily. Withdraw gradually, reducing the dose every 3 to 4 weeks: review treatment if abstinence not achieved in 3 months.	**Early morning/night cravings:** apply patch for 24H **OR** **No early morning/night cravings or patient complains of 'vivid dreams'**: apply patch for 16H each morning and remove before bedtime. Apply to dry, non-hairy skin on hip, chest or upper arm. Remove after 16/24 hours. Site next patch on different area. Avoid using the same area for several days
Nicotine Inhalator (15mg cartridge)	Initially use between 6 and 12 cartridges (15mg nicotine per cartridge) a day for up to 8 weeks. Then reduce number of cartridges by half over next 2 weeks. Then stop completely after a further 2 weeks. Review treatment if abstinence not achieved within 3 months.	Inhale when urge to smoke occurs or to prevent cravings. The amount of nicotine from 1 puff is less than that from a cigarette, therefore it may be necessary to inhale more often than when smoking a cigarette
Nicotine Lozenges 1mg,2mg,4mg	1 lozenge should be used every 1-2 hours when the urge to smoke occurs. If smoking less than 20 cigarettes a day use the 1mg or 2mg lozenges. If smoking more than 20 cigarettes a day use the 2mg or 4mg lozenges. Max 15 lozenges a day.	Lozenges to be allowed to dissolve slowly in the mouth periodically moving from one side of the mouth to the other. Lozenges last between 10 and 30 minutes.
Nicotine gum and spray are not approved formulations		

17.3 Interactions with Medication

Cigarette smoke is a potent inducer of the cytochrome P450 1A2 isoenzyme. Various medications are metabolised using this enzyme and therefore their metabolism may be affected if a patient starts or stops smoking. Listed below are medications that could be affected by a patient's abstinence from smoking. The BNF or drug SPC should be consulted for up-to-date information.

Varenicline has no clinically significant drug interactions.

Cytisinicline should not be used with anti-tuberculosis drugs. It may decrease the efficacy of combined hormonal contraceptives. The manufacturer recommends using additional contraceptive precautions during treatment with cytisinicline[3,4].

Drug	Effect of smoking cessation on drug levels[4]	Comments
Haloperidol	Serum levels may increase by up to 23% due to reduced metabolism	Haloperidol dose may need to be decreased if adverse effects such as EPSEs increase/emerge.
Clozapine	Plasma concentrations may increase significantly (up to 72%)	Decrease dose. Measure levels before quitting, and 2 weeks after: earlier if side effects occur. Significantly lower doses may be required upon discontinuation of smoking.
Olanzapine	Serum levels increase significantly (up to 21%)	May need to decrease dose – especially if adverse effects such as drowsiness or hypotension emerge.
Fluphenazine	Plasma levels may increase	Monitor symptoms/side-effects (EPSE), and reduce dose as necessary.
Fluvoxamine	Increased plasma levels	May need to decrease dose.
Propranolol (beta blockers)	Increased plasma levels	May need to decrease dose – monitor for increased drop in BP and heart rate.
Duloxetine	Serum levels may increase (up to 50%)	May need to decrease dose.
Flecainide	Increased plasma levels.	May need to decrease dose.
Insulin	May need less insulin when smoking has been stopped (nicotine causes release of catecholamines, and smoking decreases absorption of insulin.)	Review dose of insulin and monitor for hypoglycaemia – may need less insulin.
Theophylline & aminophylline	Increased plasma levels- as theophylline has a narrow therapeutic window, toxicity is possible.	Decrease dose by 25 – 33% ('typically a third'[7]) within 1 week of stopping smoking. Monitor patient (for palpitations and/or nausea) as further alterations in dosage may be required.
H_2 antagonists	Smoking appears to reduce the serum levels of cimetidine and ranitidine but not famotidine.	May need to decrease cimetidine dose or use alternative H_2 antagonist.

Speak to pharmacy or consult literature for further detailed information.

17.4 NICE Guidelines

- Four pharmacotherapies have been recommended by NICE with respect to assistance in giving up smoking. NRT (nicotine replacement therapies), Varenicline, Cytisinicline and Bupropion work best with support such as the 'NHS Stop Smoking Service'. EPUT **is only offering bupropion, cytisinicline and varenicline if a full risk assessment has been carried out.** Varenicline, cytisinicline or bupropion should not be offered to young people under 18, or to breast-feeding or pregnant women.

- Bupropion, cytisinicline or varenicline should not be used in any combination.

NICE guideline NG209[7] covers support to stop smoking for everyone aged 12 and over, and help to reduce people's harm from smoking if they are not ready to stop in one go. It also covers ways to prevent children, young people and young adults aged 24 and under from taking up smoking. The guideline brings together and updates all NICE's previous guidelines on using tobacco, including smokeless tobacco. It covers nicotine replacement therapy and e-cigarettes to help people stop smoking or reduce their harm from smoking. It does not cover using tobacco products such as 'heat not burn' tobacco.

The advice below is an extract from NICE guideline NG209.

Provision of information about using medicinally licensed nicotine-containing products

Provide information on how people who smoke can reduce the risk of illness and death (to themselves and others) by using one or more medicinally licensed nicotine-containing products. Explain that they could be used as a partial or complete substitute for tobacco, either temporarily or in the long term.

Provide the following information about nicotine:

- smoking is highly addictive mainly because it delivers nicotine very quickly to the brain and this makes stopping smoking difficult

- most smoking-related health problems are caused by other components in tobacco smoke, not by the nicotine

- nicotine levels in medicinally licensed nicotine-containing products are much lower than in tobacco, and the way these products deliver nicotine makes them less addictive than smoking.

Provide the following information about the effectiveness and safety of medicinally licensed nicotine-containing products:

- any risks from using medicinally licensed nicotine-containing products are much lower than those of smoking; nicotine replacement therapy (NRT) products have been demonstrated in trials to be safe to use for at least 5 years.

- lifetime use of medicinally licensed nicotine-containing products is likely to be considerably less harmful than smoking.

Provide information on using medicinally licensed nicotine-containing products, including:

- what forms they take
- how to use them effectively when trying to stop or cut down smoking
- long-term use to reduce the risk of relapsing
- where to get them
  the cost compared with smoking.

Identifying and quantifying people's smoking

Identifying people who smoke

At every opportunity, ask people if they smoke or have recently stopped smoking.

If they smoke, advise them to stop smoking in a way that is sensitive to their preferences and needs, and advise them that stopping smoking in one go is the best approach. Explain how stop-smoking support can help.

Discuss any stop-smoking aids the person has used before, including personally purchased nicotine-containing products.

Offer advice on using nicotine-containing products on general sale, including over-the-counter nicotine replacement therapy (NRT) and nicotine-containing e-cigarettes.

If someone does not want, or is not ready, to stop smoking in one go:

- find out about the person's smoking behaviour and level of nicotine dependence by asking how many cigarettes they smoke – and how soon after waking
- make sure they understand that stopping smoking reduces the risks of developing smoking-related illnesses or worsening conditions affected by smoking
- ask them to think about adopting a harm-reduction approach (see the section on supporting people who do not want, or are not ready, to stop smoking in one go)
- encourage them to seek help to stop smoking completely in the future
- leave the offer of help open and offer support again the next time they are in contact.

Record smoking status and all actions, discussions and decisions related to advice, referrals or interventions about stopping smoking.

Ask about their smoking status at the next available opportunity.

Identifying smoking among carers, family and other household members

At the earliest opportunity, ask if any of the following people smoke:

- partners of pregnant women
- parents or carers of people using acute or mental health services
- anyone else in the household

If partners, parents, other household members and carers do not smoke, give them positive feedback if they are present.

If they do smoke:

- encourage them to stop if they are present, and refer them to a hospital or local stop-smoking support using local arrangements if they want to stop or cut down their smoking
- if they are not present, ask the person using services to suggest they contact stop-smoking support and provide contact details.

During contact with partners, parents, other household members and carers of people using acute, maternity and mental health services:

- provide clear advice about the danger of smoking and second-hand smoke, including to pregnant women and babies – before and after birth
- recommend not smoking around the patient, pregnant woman, mother or baby (this includes not smoking in the house).

Stop-smoking interventions

Tell people who smoke that a range of interventions is available to help them stop smoking. Explain how to access them and refer people to stop-smoking support if appropriate.

Discuss with people which options to use to stop smoking, taking into account:

- their preferences, health and social circumstances
- any medicines they are taking
- any contraindications and the potential for adverse effects
- their previous experience of stop-smoking aids.

Advise people (as appropriate for their age) that the following options, when combined with behavioural support, are more likely to result in them successfully stopping smoking:

- varenicline (offered in line with NICE's technology appraisal guidance on varenicline for smoking cessation)
- Cytisinicline
- a combination of short-acting and long-acting NRT
- nicotine-containing e-cigarettes.

Advise people (as appropriate for their age) that the options that are less likely to result in them successfully stopping smoking, when combined with behavioural support, are:

- bupropion
- short-acting NRT used without long-acting NRT
- long-acting NRT used without short-acting NRT.

Adults: Ensure the following are accessible to adults who smoke:

- behavioural interventions:

    - behavioural support (individual and group)
    - very brief advice

- medicinally licensed products:
    - bupropion (see BNF information on bupropion hydrochloride)
    - nicotine replacement therapy – short and long actingvarenicline
    - cytisinicline
- nicotine-containing e-cigarettes.

For adults, prescribe bupropion, cytisinicline, varenicline, or NRT before they stop smoking:

- For bupropion agree a quit date set within the first 2 weeks of treatment, reassess the person shortly before the prescription ends.
- For varenicline agree a quit date and start the treatment 1 to 2 weeks before this date, reassess the person shortly before the prescription ends.
- For cytisinicline agree a quit date and start treatment no more than 5 days before this date, reassess the patients shortly before the prescription ends.
- For NRT agree a quit date and ensure the person has NRT ready to start the day before the quit date.

Young People: Consider NRT for young people aged 12 and over who are smoking and dependent on tobacco. If this is prescribed, offer it with behavioural support.

Do not offer varenicline, cytisinicline or bupropion to people under 18.

Offer behavioural support to people who smoke regardless of which option they choose to help them stop smoking. Explain how to access it.

Advice on medicinally licensed products

Emphasise that:

- most smoking-related health problems are caused by other components in tobacco smoke, not by the nicotine
- any risks from using medicinally licensed nicotine-containing products or other stop-smoking pharmacotherapies are much lower than those of smoking.

Explain how to use medicinally licensed nicotine-containing products correctly. This includes ensuring people know how to achieve a high enough dose to:

- control cravings
- prevent compensatory smoking
- achieve their goals on stopping or reducing the amount they smoke.

Advise people using short-acting NRT to replace each cigarette with the product they are using. Ideally, they should use this before the usual time they would have had the cigarette, to allow for the slower nicotine release from these products.

Advice on nicotine-containing e-cigarettes
(These recommendations are for people providing stop-smoking support or advice to adults)

Give clear, consistent and up-to-date information about nicotine-containing e-cigarettes to adults who are interested in using them to stop smoking (for example, see the NCSCT e-cigarette guide, and Public Health England's information on e-cigarettes and vaping).

Advise adults how to use nicotine-containing e-cigarettes. This includes explaining that:

- e-cigarettes are not licensed medicines but are regulated by the Tobacco and Related Products Regulations (2016)
- there is not enough evidence to know whether there are long-term harms from e-cigarette use
- use of e-cigarettes is likely to be substantially less harmful than smoking
- any smoking is harmful, so people using e-cigarettes should stop smoking tobacco completely.

Discuss:

- how long the person intends to use nicotine-containing e-cigarettes for
- using them for long enough to prevent a return to smoking, and
- how to stop using them when they are ready to do so.

Ask adults using nicotine-containing e-cigarettes about any side effects or safety concerns that they may experience. Report these to the MHRA Yellow Card scheme, and let people know they can report side effects directly.

Explain to adults who choose to use nicotine-containing e-cigarettes the importance of getting enough nicotine to overcome withdrawal symptoms, and explain how to get enough nicotine.

Stop-smoking pharmacotherapies in acute and mental health services

If stop-smoking pharmacotherapy is accepted, make sure it is provided immediately.

When people are discharged from hospital, ensure they have enough stop-smoking pharmacotherapy to last at least 1 week or until their next contact with stop-smoking support.

Tell them about local policies on indoor and outdoor use of nicotine-containing e-cigarettes.

Supporting people who have to stop smoking temporarily

For those who need to abstain temporarily to use acute and mental health services:

- tell them about the different types of medicinally licensed nicotine-containing products and how to use them, and
- encourage the use of medicinally licensed nicotine-containing products to help them abstain and, if possible, prescribe them.

Provide behavioural support alongside medicinally licensed nicotine-containing products to maintain abstinence from smoking while in secondary care.

Offer behavioural support to people who want or need to abstain from smoking temporarily in all settings, including closed institutions for example. Support could include:

- one-to-one or group sessions by specialist services
- discussing why it is important to reduce the harm caused by smoking (to others as well as themselves)
- encouraging people to consider other times or situations when they could stop.

Medicine dosages for people who have stopped smoking

Monitor people's use of prescribed medicines that are affected by smoking (or stopping smoking) for efficacy and adverse effects. Adjust the dosage as appropriate. Please refer to table above for example of medicines. Refer to specific information for individual medicines, such as in the BNF or summaries of product characteristics in the electronic medicines' compendium.

Discuss with people who use secondary care and their carers that it might be possible to reduce the dose of some prescribed medicines when they stop smoking. Also advise them to seek medical advice if they notice any side effects from changing the amount they smoke.

Supporting people who do not want, or are not ready, to stop smoking in one go to reduce their harm from smoking

If someone does not want, or is not ready, to stop smoking in one go, there are several harm reduction approaches:

Cutting down before stopping smoking

- with the help of one or more medicinally licensed nicotine-containing products (the products may be used as long as needed to prevent relapse to previous levels of smoking)
- without using medicinally licensed nicotine-containing products.

Smoking reduction

- with the help of one or more medicinally licensed nicotine-containing products (the products may be used as long as needed to prevent relapse to previous levels of smoking)
- without using medicinally licensed nicotine-containing products.

Temporarily not smoking

- with the help of one or more medicinally licensed nicotine-containing products
- without using medicinally licensed nicotine-containing products.

Medicinally licensed nicotine-containing products for harm reduction

Reassure people who smoke that medicinally licensed nicotine-containing products are a safe, effective way to reduce the amount they smoke or to cut down before stopping. Also:

- advise them that these products can be used as a complete or partial substitute for tobacco, either in the short or long term
- explain that using these products also helps avoid compensatory smoking and increases their chances of stopping in the longer term
- reassure them that it is better to use these products and reduce the amount they smoke than to continue smoking at their current level.

Advise people that medicinally licensed nicotine-containing products can be used for as long as they help stop them going back to previous levels of smoking.

If possible, prescribe medicinally licensed nicotine-containing products. Otherwise, encourage people to ask their GP or pharmacist for them, or tell them where they can buy the products themselves.

If more intensive support is needed, refer to stop-smoking support.

Supporting people cutting down or stopping temporarily

If people who set out to reduce the amount they smoke or to stop temporarily have been successful, assess how motivated they are to:

- maintain that level
- reduce the amount they smoke even more
- stop completely.

At appropriate intervals, measure people's exhaled breath for carbon monoxide to gauge their progress and help motivate them to stop smoking. Ask them whether daily activities, for example climbing the stairs or walking uphill, have become easier. Use this feedback to prompt discussion about the benefits of cutting down and, if appropriate, to encourage them to cut down even more or stop completely.

Offer medicinally licensed nicotine-containing products, as needed, to help prevent a relapse among people who have reduced the amount they smoke.

NOTE:
E-cigarettes/vapes are not prescribable items. This advice should be used in conjunction with the EPUT ‘Smoke-free Procedure’ (CPG32) which governs the use of e-cigarettes on Trust premises.

17.5 Reporting adverse reactions to e-cigarettes and vaping

The MHRA have issued advice[6] on reactions to e-cigarettes and vaping. They ask healthcare professionals to be vigilant for any suspected side effects or safety concerns associated with e-cigarette use or vaping (including lung injury) and report them to the

MHRA via the Yellow Card Scheme. The article provides definitions of e-cigarette or vaping associated lung injury (EVALI) to facilitate identification.

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