NHS
Greater East Midlands
Commissioning Support Unit

GEM

Greater East Midlands Commissioning Support Unit in association with
Lincolnshire Clinical Commissioning Groups, Lincolnshire Community Health Services,
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GUIDANCE ON THE PRESCRIBING OF SMOKING CESSATION THERAPY

- **Smoking cessation services are most effective if patients are offered a combination of behavioural support and pharmacotherapy.**
- **To ensure the most effective use of NHS resources, patients requiring pharmacotherapy to support smoking cessation should be referred into a smoking cessation service (i.e. Phoenix Smoking Cessation Service).**
- **Nicotine Replacement Therapy (NRT), varenicline or bupropion should only be prescribed as part of a smoking cessation programme where a smoker makes a commitment to stop smoking and sets a stop date.**
- **Initial therapy should only be prescribed to last until two weeks after the stop date; at this point the patient needs to be reviewed to ensure that the quit attempt is still ongoing.**
- **Individuals should only receive a maximum of 12 weeks pharmacotherapy related to any one quit attempt. If further supplies are required to prevent the occurrence of craving, individuals should be advised to purchase these themselves. There may be a minority of patients on varenicline that require an additional 12 week course to reduce the risk of relapse.**
- **A gap of 3 months from the last appointment (12 weeks) should be maintained between repeated quit attempts for the majority of smokers. This will ensure that individuals are sufficiently motivated prior to setting another quit date and will avoid the risk of continuous repeat prescribing of NRT where success may be severely limited. In exceptional circumstances, particularly where the quit attempt is interrupted by a traumatic event, the individual may reset their quit date and continue with pharmacotherapy for an extended period.**
- **Nicotine replacement therapies (NRT) should not be prescribed for individuals who wish to reduce the amount they smoke but have not agreed to stop smoking, as this level of support is not currently commissioned in Lincolnshire**
- **A successful quit attempt is dependent upon the individual being sufficiently motivated and compliant with therapy. To maximize engagement, patient choice should be taken into account, subject to contraindications and potential for adverse reactions. National guidance does not recommend one form of pharmacotherapy in preference to another; local figures suggest that higher quit rates are obtained with varenicline.**
- **Despite the evidence that varenicline is associated with superior long-term quit rates, the wide range of adverse effects, cautions and contra-indications associated with this form of pharmacotherapy mean that it can only be initiated following full consideration of risks and benefits by the patient's GP. Varenicline tablets 500microgram and 1mg are on the *Lincolnshire Joint Formulary*; designation GREEN.**
- **Evidence suggests that bupropion therapy does not achieve quit rates as high as those achieved by NRT or varenicline. Nonetheless, the product retains a third line role and may be particularly useful in ex-smokers relapsing after a prolonged period who have previously used this product to support a successful quit attempt. Bupropion sustained release tablets 150mg (*Zyban*)**

remain on the *Lincolnshire Joint Formulary* as a third line choice; designation GREEN.

- **Neither bupropion nor varenicline should be used concurrently with nicotine replacement therapies.**
- **The majority of people requiring NRT as part of a smoking cessation programme should be prescribed a long-acting transdermal patch in combination with an immediate release, short-acting product to counteract cravings. Where short-acting NRT products are prescribed as monotherapy, the maximum dose for each product is as stated in the *BNF* and product SPC. When a short-acting NRT product is used in combination with a long-acting nicotine transdermal patch, the maximum dose of the short acting product should be reduced to half the stated maximum dose. Combination NRT prescribing should never involve more than two formulations, one long-acting and one short-acting.**
- **Transdermal nicotine patches are an effective way of delivering background continuous nicotine replacement therapy. For the majority of patients, a 16 hour patch is preferred with the starting dose based on the individual's previous smoking habit. A 24 hour patch is indicated for those smokers usually requiring their first cigarette within a few minutes of waking and for shift workers with unpredictable work patterns. The available patches are comparably priced. Due to the preference for a 16 hour patch, the *Nicorette Invisipatch* (all strengths) is approved for inclusion in the *Lincolnshire Joint Formulary* designation GREEN. The *NiQuitin* range of patches (all strengths) offer 24 hour cover and are also approved for *Formulary* inclusion; designation GREEN. *Nicotinell* patches are classed as non-formulary and should not be prescribed.**
- **If nicotine chewing gums are prescribed, mint flavours are often more palatable and are better tolerated by most people. *Nicorette* icy white flavour gum is advocated as the first line product of choice and is approved for inclusion in the *Lincolnshire Joint Formulary*; designation GREEN.**
- ***NiQuitin Lozenge* 2mg and 4mg and *NiQuitin Minis Lozenges* 1.5mg and 4mg are advocated first line where a short-acting lozenge is indicated. Both formulations are approved for inclusion in the *Lincolnshire Joint Formulary* and designated GREEN. *NiQuitin* orodispersible film 2.5mg has already been evaluated by PACEF and designated RED-RED. It is not approved for use through the *Joint Formulary* and should not be prescribed. Due to current supply problems with *NiQuitin Minis*, *Nicorette Cools* 2mg and 4mg are also designated GREEN and included in the *Lincolnshire Joint Formulary*.**
- **Nicotine oral sprays, nasal sprays and inhalators are relatively high cost in comparison with other formulations of NRT. *Nicorette QuickMist* oromucosal spray and *Nicorette Inhalator* are approved for use through the *Lincolnshire Joint Formulary* and are designated GREEN; they should only be prescribed for those who have previously failed to quit using other forms of NRT. *Nicorette Nasal Spray* is not approved for inclusion in the *Joint Formulary* and should not be prescribed.**
- **Electronic cigarettes are currently not classed as medicines and therefore do not have to comply with the same regulatory standards as licensed nicotine replacement therapies. There are reports that the quality and nicotine content of these products varies widely between brands. There is only limited evidence of effectiveness in supporting a smoking cessation attempt, although some patients are being supported to stop smoking using electronic cigarettes through the Phoenix service. However, in most cases, where the person wants to stop smoking, evidence based pharmacotherapy using licensed NRT products, varenicline or bupropion is preferred.**

FORMULARY OF SMOKING CESSATION PRODUCTS

Drug	Indication(s)	Traffic Light and Joint Formulary Status
First line: *Short-acting nicotine formulations*		
Nicotine chewing gum (*Nicorette Gum*) icy white flavour 2mg and 4mg	Nicotine replacement as an aid to smoking cessation or reduction.	GREEN Possible first line choice of short-acting therapy. Included in the *Lincolnshire Joint Formulary.*
Nicotine lozenge (*NiQuitin Lozenge*) 2mg and 4mg	Nicotine replacement as an aid to smoking cessation or reduction.	GREEN Possible first line choice of short-acting therapy. Included in the *Lincolnshire Joint Formulary.*
Nicotine lozenge (*NiQuitin Minis Lozenges*) 1.5mg and 4mg	Nicotine replacement as an aid to smoking cessation or reduction.	GREEN Possible first line choice of short-acting therapy. Included in the *Lincolnshire Joint Formulary.*
Nicotine lozenge (Nicorette Cools) 2mg and 4mg	Nicotine replacement as an aid to smoking cessation or reduction.	GREEN Possible first line choice of short-acting therapy. Included in the *Lincolnshire Joint Formulary* due to current supply problems with *NiQuitin Minis*..
First line: *Long-acting transdermal nicotine formulations*		
Nicotine transdermal patch 10mg, 15mg and 25mg(16 hours) (*Nicorette Invisipatch)*	Nicotine replacement as an aid to smoking cessation or reduction.	GREEN Possible first line choice of long-acting therapy. For the majority of patients, a 16 hour patch is preferred with the starting dose based on the individual's previous smoking habit. Included in the *Lincolnshire Joint Formulary*
Nicotine transdermal patch 7mg, 14mg, 21mg (24 hours) (*NiQuitin*)	Nicotine replacement as an aid to smoking cessation or reduction.	GREEN Possible first line choice. A 24 hour patch is indicated for those smokers usually requiring their first cigarette within a few minutes of waking and for shift workers with unpredictable work patterns. Included in the *Lincolnshire Joint Formulary*
Second line: *Short-acting nicotine formulations*		
Nicotine inhalation cartridge plus mouthpiece (*Nicorette Inhalator*) 15mg	Nicotine replacement as an aid to smoking cessation or reduction.	GREEN Possible second line choice of short-acting therapy. Included in the *Lincolnshire Joint Formulary.*
Nicotine oromucosal spray (*Nicorette QuickMist*) 1mg per dose	Nicotine replacement as an aid to smoking cessation	GREEN Possible second line choice of short-acting therapy. Included in the *Lincolnshire Joint Formulary.*
Others		
Bupropion 150mg sustained release tablets (*Zyban*)	Aid to smoking cessation	GREEN 3rd line choice Included in the *Lincolnshire Joint Formulary*
Varenicline 500microgram/1mg tablets (*Champix)*	Smoking cessation	GREEN Possible first line choice. Included in the *Lincolnshire Joint Formulary*

Products not listed on this Formulary are not recommended for use and should not be prescribed.

Introduction

General guidance

National Institute for Clinical Excellence (NICE) *Quality Standard 43 - Smoking cessation: supporting people to stop smoking* (August 2013)

NICE emphasize the importance of:

(1) healthcare practitioners proactively asking patients if they smoke and offering identified smokers advice on how to stop.
(2) offering smokers who wish to stop a referral to an evidence-based smoking cessation service.
(3) ensuring that people being supported to stop by an evidence-based smoking cessation service are offered both behavioural support and pharmacotherapy in combination as this approach has the highest likelihood of success.
(4) ensuring that people being supported to stop smoking are offered a full course of pharmacotherapy.
(5) ensuring that people being supported to stop smoking set a quit date and are assessed for carbon monoxide levels 4 weeks after that date.

Guidance on the use of nicotine replacement therapy to reduce but not stop smoking

NICE Public Health Guidance 45 - *Tobacco: harm-reduction approaches to smoking* (June 2013)

This PHG acknowledges that people:

- may not be able (or may not want) to stop smoking in one step.
- may want to stop smoking without necessarily giving up nicotine.
- may not be ready to stop smoking, but may want to reduce the amount they smoke.

PACEF Recommendations

(1)Smoking cessation services are most effective if patients are offered a combination of behavioural support and pharmacotherapy. This was backed up by local figures published by Lincolnshire Community Health Services in May 2014.

(2)To ensure the most effective use of NHS resources, patients requiring pharmacotherapy to support smoking cessation should be referred into a smoking cessation service.

(3) Lincolnshire County Council has confirmed that NICE PHG 45 is currently not commissioned within Lincolnshire. As a result of this, nicotine replacement therapies (NRT) should not be prescribed for individuals who wish to reduce the amount they smoke but have not agreed to stop smoking.

Guidance on the appropriate interval between treatment episodes

NICE Public Health Guidance 10 - *Smoking cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach communities* (February 2008)

NICE recommendations state that:

- Following an unsuccessful quit attempt using NRT, varenicline or bupropion, a subsequent quit attempt should not be supported within 6 months unless special circumstances have hampered the person's initial attempt to stop smoking, when it may be reasonable to try again sooner.
- It may take many attempts before a person can successfully quit smoking and encouragement needs to be maintained throughout.

Department of Health - *Local Stop Smoking Services - Key updates to the 2011/12 service delivery and monitoring guidance for 2012/13*

This is a good practice guide for the provision of smoking cessation services and provides some guidance on the recommended interval between treatment episodes:

- When a client has not managed to stop smoking, there is no definitive period of time required between the end of a treatment episode and the start of another. The stop smoking adviser should use discretion and professional judgement when considering whether a client is ready to receive support to immediately attempt to stop again. If this is the case, the client must start a new treatment episode, attend one session of a structured multi-session intervention, consent to treatment and set a quit date with a stop-smoking adviser.

PACEF Recommendations

(4) Following discussion between representatives from the Phoenix Smoking Cessation Service and Lincolnshire Public Health it is recommended that a gap of 3 months from the last appointment (12 weeks) should be maintained between repeated quit attempts for the majority of smokers. This will ensure that individuals are sufficiently motivated prior to setting another quit date and will avoid the risk of continuous repeat prescribing of NRT where success may be severely limited.

In exceptional circumstances, particularly where the quit attempt is interrupted by a traumatic event, the individual may reset their quit date and continue with pharmacotherapy for an extended period.

Pharmacotherapy

NICE Public Health Guidance 10 - *Smoking cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach communities* (February 2008)

The main recommendations relating to the use of pharmacotherapy are as follows:

- Offer NRT, varenicline or bupropion, as appropriate, to people who are planning to stop smoking.
- Before prescribing a treatment take into account the person's intention and motivation to quit and how likely it is they will follow the course of treatment. Consideration should be given to which treatments the individual prefers, whether they have attempted to stop before (and how), and if there are medical reasons why they should not be prescribed particular pharmacotherapies.
- Offer advice, encouragement and support, including referral to the NHS Stop Smoking Service, to help people in their attempt to quit.
- NRT, varenicline or bupropion should normally be prescribed as part of an abstinent-contingent treatment, in which the smoker makes a commitment to

stop smoking on or before a particular date (target stop date). The prescription of NRT, varenicline or bupropion should be sufficient to last only until 2 weeks after the target stop date. Normally, this will be after 2 weeks of NRT therapy, and 3–4 weeks for varenicline and bupropion, to allow for the different methods of administration and mode of action. Subsequent prescriptions should be given only to people who have demonstrated, on re-assessment that their quit attempt is continuing.

PACEF Recommendation
(5)A successful quit attempt is dependent upon the individual being sufficiently motivated and compliant with therapy. To maximize engagement, patient choice should be taken into account, subject to contraindications and potential for adverse reactions. National guidance does not recommend one form of pharmacotherapy in preference to another; local figures suggest that higher quit rates are obtained with varenicline.

Duration of treatment

The recommended duration of treatment for each form of pharmacotherapy is tabulated below:

	Maximum length of treatment
Nicotine Replacement Therapy	12 weeks
Bupropion (*Zyban*)	7 to 9 weeks
Varenicline (*Champix*)	12 weeks (but can be repeated in abstinent individuals to reduce risk of relapse).

PACEF Recommendation
(6)In accordance with guidance from Phoenix Smoking Cessation Service and Lincolnshire Public Health, it is recommended that individuals should only receive a maximum of 12 weeks pharmacotherapy related to any one quit attempt. If further supplies are required to prevent the occurrence of craving, individuals should be advised to purchase these themselves. There may be a minority of patients on varenicline that require an additional 12 week course to reduce the risk of relapse.

Choice of therapy

The table below illustrates that NRT (in a variety of formulations) and varenicline are widely prescribed in all four Lincolnshire Clinical Commissioning Groups (CCGs): in comparison, bupropion is prescribed very infrequently. NRT is most commonly prescribed in a patch formulation:

Product	**LECCG Items**	**LWCCG Items**	**SLCCG Items**	**SWLCCG Items**
Bupropion 150mg SR tablets (*Zyban*)	21	26	13	22
Varenicline 500microgram/1mg tablets (*Champix)*	1,575	1,009	731	591
NRT				
NRT patches	1281	1094	583	474
NRT chewing gum	164	129	111	71
NRT lozenges/tablets/strips	364	270	154	107

NRT sprays	289	222	101	82
Nicorette inhalator	512	377	220	185

Figures derived from CCG prescribing data for the 4th quarter of 2013/14

Varenicline (*Champix*)

Varenicline is a selective nicotine receptor partial agonist used as an aid for smoking cessation. Clinical evidence published as part of NICE Technology Appraisal 123 supports claims that varenicline is more effective than NRT in terms of long term quit rates. Local data from the LCHS smoking cessation report published in May 2014 also supports this conclusion.

Varenicline (*Champix*) is only licensed for use in adults aged over 18. Treatment should usually be initiated 1-2 weeks prior to the target stop date, with an initial dose of 500mcg once daily for three days increasing to 500mcg twice daily for 4 days; the usual maintenance dose is 1mg twice daily for 11 weeks, leading to 12 weeks treatment in total. The maintenance dose can be reduced to 1mg twice daily if not tolerated. Sometimes, Phoenix recommends tapering of varenicline dosage towards the end of the 12 weeks. As stated above, the 12 week course can be repeated in abstinent individuals to reduce the risk of relapse, although this goes beyond the 12 week programme of support that Phoenix is commissioned to provide.

Varenicline is associated with a wide range of adverse effects, most commonly gastrointestinal disturbances, appetite changes, dry mouth, taste disturbance, headache, drowsiness, dizziness, sleep disorders and abnormal dreams. It is contraindicated in pregnancy and when breast feeding. In 2008, the MHRA issued a safety alert highlighting a potential association between varenicline therapy and increased risk of suicidal thoughts and behaviour. Patients should be advised to stop treatment and contact their doctor immediately if they develop suicidal thoughts, agitation or depressed mood. Those with a history of psychiatric illness should be monitored closely while taking varenicline. Varenicline should also be used with caution in those with a history of cardiovascular disease and in those with a predisposition to seizures.

Decision making around the appropriateness of initiation of varenicline in an individual patient requires access to the individual patient record. As a result of this, the final decision as to whether varenicline treatment is clinically appropriate remains the responsibility of the clinician that prescribes the therapy.

PACEF Recommendation

(7)Despite the evidence that varenicline is associated with superior quit rates, the wide range of adverse effects, cautions and contra-indications associated with this form of pharmacotherapy mean that it can only be initiated following full consideration of risks and benefits by the patient's GP. Varenicline tablets 500microgram and 1mg remain on the *Lincolnshire Joint Formulary*; designation GREEN.

Bupropion hydrochloride (*Zyban*)

Bupropion (*Zyban*) has previously been used as an antidepressant. Its mode of action in smoking cessation is not clear and may involve an effect on noradrenaline and dopamine neurotransmission.

Bupropion (*Zyban*) is only licensed for use in adults aged over 18; it should only be used in those smoking at least 15 cigarettes a day and weighing at least 45kg.

The dose of bupropion is 150mg initially once daily for 6 days then twice daily for a period of 7 to 9 weeks, commencing treatment 1 to 2 weeks before target stop date.

Bupropion is associated with a number of adverse effects including: dry mouth, gastrointestinal disturbances, taste disturbance, agitation, anxiety, dizziness, depression, headache, impaired concentration, insomnia, tremor, fever, pruritus, rash and sweating. It is contraindicated in those with severe hepatic cirrhosis, CNS tumour, history of seizures, eating disorders or bipolar disorder. It should be used with caution in the elderly and in those with a predisposition to seizures, those on concomitant drug therapy which lowers the seizure threshold, those with a history of alcohol abuse and those with a history of head trauma or diabetes.

PACEF Recommendation
(8)Evidence suggests that bupropion therapy does not achieve quit rates as high as those achieved by NRT or varenicline. Nonetheless, the product retains a third line role and may be particularly useful in ex-smokers relapsing after a prolonged period who have previously used this product to support a successful quit attempt. Bupropion sustained release tablets 150mg (*Zyban*) remain on the *Lincolnshire Joint Formulary* as a third line choice; designation GREEN.

Nicotine Replacement Therapy

There are several different types of formulation available:

- Patches – controlled release patches delivering a continuous dose of background nicotine over a 16 to 24 hour period.
- Oral products - chewing gum, lozenges, sublingual tablets, oral film strips, oral or nasal sprays – designed to provide a short-acting, additional dose of nicotine to relieve intense craving.
- Inhalator devices – provide an inhaled dose of nicotine; the device mimics the delivery system of a cigarette or e-cigarette.

Selection of NRT

NICE Public Health Guidance 10 - *Smoking cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach communities* (February 2008)

- Consider offering a combination of a long-acting nicotine patch with a shorter acting form of NRT (e.g. gum, inhalator, lozenge or nasal spray) to people who show a high level of dependence on nicotine or who have found single forms of NRT inadequate in the past.
- Explain the risks and benefits of using NRT to young people aged from 12 to 17, women who are pregnant or breastfeeding and those with unstable cardiovascular disorders.
- To maximise the benefits of NRT, people should be strongly encouraged to use behavioural support in conjunction with pharmacotherapy as part of their quit attempt.
- NRT, varenicline and bupropion should not be used in combination.

PACEF Recommendation
(9)The majority of people requiring NRT as part of a smoking cessation programme should be prescribed a long-acting transdermal patch in

combination with an immediate release, short-acting product to counteract cravings. Where short-acting NRT products are prescribed as monotherapy, the maximum dose for each product is as stated in the *BNF* and product SPC. When a short-acting NRT product is used in combination with a long-acting nicotine transdermal patch, the maximum dose of the short acting product should be reduced to half the stated maximum dose. Combination NRT prescribing should never involve more than two formulations, one long-acting and one short-acting.

Transdermal patches

There are a variety of patches licensed for use over 16 or 24 hours. The 24 hour patch is more suitable for:

- Heavily dependent smokers usually requiring their first cigarette within a few minutes of waking.
- Shift workers, particularly those with unpredictable work patterns.

The 16 hour patch is more suitable for:

- Those who crave their first cigarette at least 1 hour after waking.
- Patches licensed for use over 24 hours can be used for patients requiring 16 hour cover if the person is advised to remove them at bedtime.

A common adverse effect of nicotine is sleep disturbance and, for the majority of people, the 16 hour patch is the most appropriate. Local prescribing data indicates that the 16 hour patches are the most frequently prescribed.

The strength of the patch prescribed is usually dependent upon the person's past smoking habit, with the strength of the patch reduced over time. Patches should be applied daily, normally in the morning, to a clean dry, non-hairy area of skin on the hip, trunk or upper arm. Patch sites need to be rotated to avoid skin irritation. Patches should not be applied to broken or inflamed skin and are unsuitable for those with skin disorders. Local experience suggests that *Niquitin* clear patches may preferred in people who suffer from skin problems. Where transdermal patches are used within this context, the patch should only be applied to areas of skin not affected by the skin disorder.

Patches need to be disposed of correctly (i.e. by folding in half) to prevent children and/or pets being accidentally exposed to nicotine.

As illustrated by the table below, patches are comparably priced:

Cost comparison: *Nicotine transdermal patches*

Patch	**Strength**	**Cost (£ per 7 patches)**
Nicorette Invisipatch	10mg/16hrs	£9.97
	15mg/16hrs	£9.97
	25mg/16hrs	£9.97 or £16.35 for 14
Nicotinell	7mg/24 hrs	£9.11
	14mg/24hrs	£9.40
	21mg/24hrs	£9.97 or £24.51 for 21
Niquitin	7mg/24 hrs	£9.97
	14mg/24hrs	£9.97
	21mg/24hrs	£9.97 or £18.79 for 14

Cost per course: *Nicotine transdermal patches*

Patch	Number cigarettes/day	Dose regimen	Cost per quit attempt
Nicorette Invisipatch (16 hour patch)	>10/day	25mg daily for 8 weeks then 15mg daily for 2 weeks then 10mg daily for 2 weeks (12 weeks)	£119.64
	<10/day	15mg daily for 8 weeks then 10mg daily for 4 weeks (12 weeks)	£119.64
	Smoking reduction	25mg daily until smoking <10 cigarettes a day then 15mg daily for 8 weeks then 10mg daily for 4 weeks	£119.64 +
Nicotinell (24 hour patch)	>20/day	21mg/24hrs daily for 3-4 weeks then 14mg/24 hours for 3-4 weeks then 7mg/24 hours for 3-4 weeks. (maximum duration 3 months)	£113.92 (based on 4 weeks use per strength patch)
	<20/day	14mg/24 hrs for 3-4 weeks then 7mg/24 hours for 3-4 weeks. (maximum duration 3 months)	£74.04 (based on 4 weeks use per strength patch)
NiQuitin (24 hour patch)	>10/day	21mg/24hrs daily for 6 weeks then 14mg/24 hours for 2 weeks then 7mg/24 hours for 2 weeks. (maximum duration 10 weeks)	£99.70
	<10/day	14mg/24hrs daily for 6 weeks then 7mg/24 hours for 2 weeks (maximum duration 8 weeks)	£79.76

PACEF Recommendation

(10)Transdermal nicotine patches are an effective way of delivering background continuous nicotine replacement therapy. For the majority of patients, a 16 hour patch is preferred with the starting dose based on the individual's previous smoking habit. A 24 hour patch is indicated for those smokers usually requiring their first cigarette within a few minutes of waking and for shift workers with unpredictable work patterns. The available patches are comparably priced. Due to the preference for a 16 hour patch, the *Nicorette Invisipatch* (all strengths) is approved for inclusion in the *Lincolnshire Joint Formulary* designation GREEN. The *NiQuitin* range of patches (all strengths) offer 24 hour cover and are also approved for *Formulary* inclusion; designation GREEN. *Nicotinell* patches are classed as non-formulary and should not be prescribed.

Short-acting nicotine replacement products

There are a variety of nicotine containing formulations designed to provide a small dose of nicotine to help relieve intense cravings. The quickest acting formulation is the nasal spray, followed by the oral spray. Lozenges release nicotine faster than chewing gum and seem to be a more acceptable formulation for many patients. Choice of adjunct therapy is largely guided by client preference and is influenced by past smoking habits.

All short-acting nicotine replacement products can be used as monotherapy, although national guidance, supported by local data, suggests that higher quit rates are obtained if short-acting products are used in combination with longer-acting transdermal nicotine patches. If used in combination with a patch, the maximum

recommended dose for each product is half of the maximum recommended dose if used as monotherapy.

Oral products

Examples: chewing gum, lozenges, sublingual tablets, oral film strips, oral or nasal sprays.

Oral products should be used with caution in those with oesophagitis, gastritis or peptic ulcers because, if swallowed, nicotine can aggravate these conditions. Acidic beverages, such as coffee or fruit juice, may decrease absorption through the buccal mucosa and should be avoided for 15 minutes before the intake of oral nicotine replacement therapy.

Chewing Gums

- The recommended dose is one 2mg gum to be chewed when the urge to smoke occurs. The gum should be chewed until the taste becomes strong, and then rested between the cheek and gum; when the taste starts to fade, chew again and repeat the process. One piece of gum used in this way should last for approximately 30 minutes.
- If used as monotherapy, the recommended dose for those smoking fewer than 20 cigarettes per day is 2mg. For those smoking over 20 cigarettes a day, requiring more than 15 pieces of 2mg gum, the 4mg strength should be used; care should be taken not to exceed the maximum dose.
- Prescribing data indicates that chewing gum is not as popular as it used to be, although it is still the short-acting product of choice for some individuals.
- There is some variation in price between the different brands and flavours, although generally the larger pack sizes are the most cost effective options. Smaller pack sizes should be prescribed initially to avoid unnecessary wastage if treatment needs to be changed in the middle of the course.
- Nicotine chewing gum has a very bitter taste that seems most effectively masked by mint flavours, particularly when used in the 2mg strength.
- If used in combination with nicotine patches, the 2mg strength should be used in preference to the 4mg strength. Highly dependent smokers may need the 4mg gum in combination with a nicotine patch
- Chewing gum may not be suitable for denture wearers as it can stick to and damage dentures.

Cost comparison: *Nicotine chewing gums*

Product	**Strength**	**Maximum dose if used as monotherapy (halved if used in conjunction with nicotine patches)**	**Price/pack size**
Nicorette gum	2mg	15 gums/day	Original, freshmint, mint & fresh fruit (mint & fresh fruit 105 pack size only) £3.25 (30), £9.27 (105) £14.82 (210) Icy white £3.42 (20) £9.37 (105)
	4mg	15 gums/day	Original, freshmint, mint & fresh fruit (mint & fresh fruit 105 pack size only) £3.99(30), £11.30 (105), £18.24

			(210) Icy white £11.48 (105)
Nicotinell gum	2mg	25 gums/day	Mint , fruit £1.45 (12), £2.67 (24), £8.26 (96) Icemint £6.69 (72) Liquorice £2.67 (24), £8.26 (96)
	4mg	15 gums/day	Mint, rruit £1.57 (12), £3.30 (24), £10.26 (96) Icemint £8.29 (72) Liquorice £3.30 (24), £10.26 (96)
Niquitin gum	2mg & 4mg	15 gums/day	Mint £1.71 (12), £3.25 (24), £9.97 (96)

Product	**Max daily dose**	**Cost /day**
Chewing gums		
***Nicorette* gum**		
original & fresh mint	**15 x 2mg**	**£1.06**
mint & fresh fruit	**15 x 2mg**	**£1.32**
original & fresh mint	**15 x 4mg**	**£1.30**
mint & fresh fruit	**15 x 4mg**	**£1.61**
Nicotinell		
mint ,fruit .liquorice	25 x 2mg If using 15/day	£2.15 £1.29
ice mint	25 x 2mg If using 15/day	£2.32 £1.39
mint, fruit. liquorice	15 x 4mg	£1.60
ice mint	15 x 4mg	£1.73
NiQuitin		
mint	15 x 2mg or 15 x 40mg	£1.56

PACEF Recommendation:
(11) If nicotine chewing gums are prescribed, mint flavours seem to be more palatable and better tolerated by most people. As a result of this, and in the absence of any clear difference in price between the major brands and flavours, *Nicorette* icy white flavour gum is advocated as the first line product of choice and is approved for inclusion in the *Lincolnshire Joint Formulary*; designation GREEN.

Lozenges and microtablets

Based on current prescribing trends lozenges are a popular formulation of oral short-acting nicotine. One lozenge should be used every 1 to 2 hours when the urge to smoke occurs. The lozenge should be allowed to dissolve in the mouth and periodically moved from one side of the mouth to the other; each lozenge should last for 10 to 30 minutes. The mini-lozenge is currently the most popular formulation as it is much smaller than alternatives, although slightly more expensive. Due to variation in pack size, it is difficult to compare the cost of different products. Generally, it is more cost effective to prescribe in larger packs, particularly where the prescriber can be confident of patient preference. If used in combination with nicotine patches, 1.5mg or 2mg strengths should be used in preference to the 4mg.

Oral dispersible films (NiQuitin Strips)

There is currently only one oral dispersible film holding a UK marketing authorisation, *NiQuitin Strips*. PACEF evaluated the product in January 2014 and did not consider the available evidence sufficient to support inclusion in the *Lincolnshire Joint Formulary.* As a result of this, nicotine 2.5mg orodispersible film (*NiQuitin Strips Mint*) is designated RED-RED and should not be prescribed.

Cost comparison: *Nicotine lozenges, microtablets and oral dispersible films*

Product	Strength	Maximum dose	Price/pack size
Lozenges/micro tablets			
Nicorette Cools (lozenges)	2mg	15 lozenges/day	Mint £3.18 (20), £11.48(80)
	4mg	15 lozenges/day	Mint £11.48 (80)
Nicorette Microtab (sublingual)	2mg	40tabs/day	£4.83 (30),£13.12 (100)
Nicotinell Lozenge	1mg	30 mg/day (30 loz)	Mint £1.71 (12), £4.27 (36), £9.12 (96)
	2mg	30mg/day(15 loz)	Mint £1.99 (12), £4.95 (36), £10.60(96)
NiQuitin Lozenge	2mg & 4 mg	15 lozenges/day	Original & mint £5.12 (36) £9.97 (72)
NiQuitin Minis Lozenge	1.5mg & 4mg	15 lozenges/day	Mint & Cherry £3.18 (20), £8.93 (60)
NiQuitin Strips orodispersible film	2.5mg	15 films /day	£3.51 (15),£10.85 (60)

Cost per day of treatment: *Nicotine lozenges, microtablets and oral dispersible films*

Product	Max daily dose	Cost /day
Lozenges/micro tabs		
Nicorette		
lozenges	15 x 2mg or 15 x 4mg	£2.15
Microtabs	40 x 2mg	£2.25
Nicotinell		
Lozenge	30 x 1mg	£2.85
Lozenge	**15 x 2mg**	**£1.66**
NiQuitin		
Lozenge	**15 x 2mg, 15 x 4mg**	**£2.08**
Minis Lozenge	15 x 1.5mg, 15 x 4mg	£2.23
Orodispersible film	15 x 2.5mg	£3.15

PACEF Recommendation

(12) *NiQuitin Lozenge* 2mg and 4mg and *NiQuitin Minis Lozenges* 1.5mg and 4mg are advocated first line where a short-acting lozenge is indicated. Both formulations are approved for inclusion in the *Lincolnshire Joint Formulary* and designated GREEN*. NiQuitin* orodispersible film 2.5mg has already been evaluated by PACEF and designated RED-RED. It is not approved for use through the *Joint Formulary* and should not be prescribed. Due to current supply problems with *NiQuitin Minis*, *Nicorette Cools* 2mg and 4mg are also designated GREEN and included in the *Lincolnshire Joint Formulary*.

Oral sprays, nasal sprays and inhalators

Nicotine oral spray (*Nicorette QuickMist*): patients can use one or two sprays into the mouth when the urge to smoke occurs or to prevent cravings. The spray should be released into the mouth, holding the spray as close to the mouth as possible and avoiding the lips. The patient should not inhale whist spraying and avoid swallowing for a few seconds after use. Patient experience suggests that some patients have difficulty with this technique and can experience a gagging sensation. Directing the spray to the side of the mouth can help to avoid this. Oral sprays should be used with caution in those with oesophagitis, gastritis or peptic ulcers because, if swallowed, nicotine can aggravate these conditions.

Nicotine inhalation cartridges (*Nicorette Inhalator*): the cartridges can be used when the urge to smoke occurs or to prevent cravings. The cartridge is inserted into the device and air is drawn in through the mouth piece with each use of the device lasting for approximately 5 minutes. The amount of nicotine from 1 puff of the cartridge is less than that from a cigarette and it is likely to be necessary for the person to inhale more frequently than when smoking. A single 15mg cartridge lasts for approximately 40 minutes of intense use. Care should be taken with the inhalation cartridges in those with obstructive lung disease, chronic throat disease or bronchospastic disease. The *Nicorette Inhalator* is the only option that directly mimics the physical activity of smoking. Anecdotal reports indicate that many patients continue to use the inhalator as a habit substitute even after the cartridge is empty.

Nicotine nasal spray (*Nicorette Nasal Spray*): one spray can be used in each nostril when the urge to smoke occurs up to a frequency of twice an hour. If lower doses are required the spray can be applied to just one nostril. The nasal spray can cause worsening of bronchial asthma and is associated with sneezing and local irritation.

Cost comparison: *oral sprays, nasal sprays and inhalators*

Product	**Strength**	**Maximum dose**	**Cost**
Nicorette Nasal Spray	500mcg/dose	1 spray into each nostril each nostril twice an hour maximum 64 spray/day	£13.40 (10ml – 200 doses)
Nicorette QuickMist oromucosal spray	1mg/dose	Maximum 4 sprays an hour, 64 sprays/day.	1x 13.2ml £12.12 2X13.2ml £19.14
Nicorette Inhalator inhaler plus cartridge	15mg	6 cartridges/day	4 x £4.14 20 x £14.03 36 x £23.33

PACEF Recommendation

(13) Nicotine oral sprays, nasal sprays and inhalators are relatively high cost in comparison with other formulations of NRT. *Nicorette QuickMist* oromucosal spray and *Nicorette Inhalator* are approved for use through the *Lincolnshire Joint Formulary* and are designated GREEN; they should only be prescribed for those who have previously failed to quit using other forms of NRT. *Nicorette Nasal Spray* is not approved for inclusion in the *Joint Formulary* and should not be prescribed.

Electronic cigarettes

Electronic cigarettes (or e-cigarettes) are battery powered devices that deliver on inhalation a vaporised liquid nicotine solution. Each device is comprised of a battery, atomiser and cartridge containing water, propylene glycol or glycerine, varying amounts of nicotine and flavourings such as tobacco, whisky, bubble-gum or fruit. When the user inhales, a sensor detects the airflow and heats the liquid nicotine filled cartridge to produce the vapour. This has led to the team "vaping" being used to describe the use of e-cigarettes.

Electronic cigarettes mimic a real cigarette in design, often having a 'lit' end to resemble a lit cigarette and emit a 'smoke like' vapour when the user exhales. Despite this resemblance, they do not contain tobacco, don't burn and therefore do not produce tobacco smoke.

Studies undertaken to date suggest that electronic cigarettes are less harmful than smoking conventional cigarettes. The British Medical Association (BMA) advises that "while e-cigarettes are unregulated and their safety cannot be assured, they are likely to be a lower risk than continuing to smoke." However, as yet there has been no research to assess the long term health effects of using electronic cigarettes.

At present these products are unlicensed and unregulated; there may be vast differences between brands. In particular, some brands have been found to be of poor quality and ineffective at delivering the nicotine vapour; this means the user could inhale too much or too little nicotine. While cartridges are available in a range of different nicotine strengths; some studies have found that the actual nicotine level does not correspond to that advertised. This may lead to users inhaling more or less nicotine than expected. There have also been some incidents reported in the media where e-cigarette batteries have exploded or started fires.

The MHRA announced in June 2013 a government intention to regulate electronic cigarettes and other nicotine containing products (NCPs) as medicines. There is an expectation that the first NCPs will be regulated as early as 2014.

PACEF Recommendation

(14) Electronic cigarettes are currently not classed as medicines and therefore do not have to comply with the same regulatory standards as licensed nicotine replacement therapies. There are reports that the quality and nicotine content of these products varies widely between brands. There is only limited evidence of effectiveness in supporting a smoking cessation attempt, although some patients are being supported to stop smoking using electronic cigarettes through the Phoenix service. In most cases where the person wants to stop smoking, evidence based pharmacotherapy using licensed NRT products, varenicline or bupropion is preferred.

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