



# Hertfordshire Guidance: Stop smoking medication

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## Introduction

Helping an individual to stop smoking includes understanding their lifestyle, personal preferences and previous experience of attempting to stop smoking before discussing the various treatment options available. Using medication effectively with behavioural support increases an individual's chances of stopping smoking by up to 4 times. It is therefore important to provide a choice of interventions, accompanied by supporting information regarding relative chances of success, the effects and possible side effects of different treatment options as well as ensuring ease of access to their treatment of choice. This guidance is in line with NICE guidance, the National Centre for Smoking Cessation and Training (NCSCT) recommendations and the Summary of Product Characteristics for the included products. This guidance is intended to improve and standardise practice in Hertfordshire and reduce unnecessary prescribing costs. Separate guidance is available for clinicians working in hospital settings.

### Contents of guidance:

- Updates and replaces 'Hertfordshire Guidance: Stop smoking medication (published December 2016)
- Includes specific recommendations for pregnant women and women who are lactating.
- Includes specific recommendations for people with a diagnosed mental health condition.
- Includes a specific recommendation on the use of electronic cigarettes (also known as e-cigarettes)
- Varenicline (Champix®) is no longer a black triangle medication. The changes to the varenicline Summary of Product Characteristics (SPCs) are highlighted in this guidance.

### Key changes from the December 2016 guidance

- Individuals who choose to use nicotine replacement therapy (NRT) to stop smoking may be supplied with a single NRT product ONLY
- Only NRT patches may be supplied unless the individual has a serious reaction to patches or skin disorder (pregnant women may still be supplied with two NRT products if this is clinically indicated)
- Stop smoking advisors in GP practices must use the NRT voucher system (letter of recommendation) to supply NRT
- Individuals should be encouraged to self-fund a second nicotine containing product if appropriate (e-cigarette or NRT)

### Who should use this guidance

- All health and care professionals (including GPs, community pharmacists and stop smoking advisors) who deliver stop smoking services and/or give advice to people in Hertfordshire to help them stop smoking should refer to this guidance.

### Population groups covered

- This guidance relates to people of any age in Hertfordshire who are motivated to stop smoking and have set a quit date. The guidance also contains recommendations for 3 specified population groups: women who are pregnant or lactating, young people (under 18 years of age) and people with a mental health condition.
- Please refer to [Hertfordshire Guidance on Tobacco Harm Reduction](#) (published February 2015) for advice to people who are not ready to stop smoking.
- Please note; this guidance should be used in conjunction with NHS Trust policies when delivering stop smoking services and/or advice to hospital patients, visitors or staff who smoke.

### Reimbursement of costs of medicines

- Reimbursement of costs will only be made for medication prescribed or dispensed in line with this guidance.

- In addition, the person attempting to stop smoking must set a quit date and their details must be recorded on QuitManager or alternative database approved by Hertfordshire County Council.
- An audit of prescribing costs will be undertaken and any prescribing or dispensing that does not comply with this guidance may not be reimbursed.

## Future updates of this guidance

- This guidance will be reviewed in October 2019 or earlier if required (e.g. new national guidance published or significant changes to clinical effectiveness or the safety profile of any relevant medication).

## Recommendations

### Section A: DO NOT USE

- A1: Combinations of Nicotine Replacement Therapy (NRT) with varenicline (Champix<sup>®</sup>) or bupropion (Zyban<sup>®</sup>) should **NOT** be prescribed, supplied or recommended. This is in accordance with NICE guidance.
- A2: E-cigarettes or other nicotine containing devices should **NOT** be prescribed but can be recommended to help an individual to reduce smoking or stop smoking altogether (self-funded).

### Section B: prescribing and dispensing for adults not in specified population group

- B1: The only medicines approved for stopping smoking are NRT, varenicline (Champix<sup>®</sup>) and bupropion (Zyban<sup>®</sup>). All three should be offered as equal first line treatments where clinically appropriate. This should be in combination with behavioural support to give all people who smoke the optimum chance of success of stopping smoking on every occasion. This is in accordance with NICE guidance.
- B2: Combination NRT i.e. two NRT products, should be recommended if appropriate. This is in accordance with NICE guidance. In Hertfordshire, only NRT patches may be supplied as part of a stop smoking service. Individuals (unless pregnant) should be encouraged to self-fund a second nicotine containing product (or use varenicline if clinically appropriate). Individuals who have a serious reaction to patches (local skin reaction is normal) or skin disorder may be supplied with an intermittent NRT product.
- B3: E-cigarettes should be supported and encouraged to reduce smoking or stop smoking altogether (self-funded) and may be used in combination with NRT (single or combination).
- B4: Prescriptions for NRT, varenicline (Champix<sup>®</sup>) or bupropion (Zyban<sup>®</sup>) should not exceed a **maximum of 2 weeks at a time** (unless in extenuating circumstances) and for a maximum total of 12 weeks. Hertfordshire Public Health Service will only fund a maximum of 12 weeks treatment. If the patient wants to continue to use NRT after this time, then this should be self-funded. This is in accordance with the Hertfordshire County Council's service specification for the delivery of stop smoking services (see Appendix 3).
- B5: Varenicline (Champix<sup>®</sup>) or bupropion (Zyban<sup>®</sup>) may be offered to people with unstable cardiovascular disorders, subject to clinical judgement. This is in accordance with NICE guidance.
- B6: Ensure people who use other medicines that are affected by smoking (or stopping smoking) are monitored, and the dosage adjusted if appropriate. Medicines that are affected include: clozapine, olanzapine, theophylline, chlorpromazine and methadone, insulin and warfarin. This is not an exhaustive list and further information can be found here:  
<http://www.oxfordhealthformulary.nhs.uk/docs/Which%20medicines%20need%20dose%20adjustment%20when%20a%20patient%20stops%20smoking%20UKMI%20QA%20Aug%202012.pdf>  
(UK Medicines Information 2012).

*NOTE: please also see section F (prescribing and dispensing recommendations relating to all population groups).*

## Section C: prescribing and dispensing for women who are pregnant or lactating

C1: **DO NOT** prescribe varenicline or bupropion to pregnant women. Varenicline (Champix<sup>®</sup>) and bupropion (Zyban<sup>®</sup>) are contraindicated in pregnancy and should not be prescribed or supplied to pregnant women. This is in accordance with NICE guidance and the Summary of Product Characteristics.

C2: Bupropion (Zyban<sup>®</sup>) and its metabolites are excreted in breast milk and should be used with caution by women who are lactating. A decision on whether or not to continue breastfeeding with concomitant use of bupropion (Zyban<sup>®</sup>) should be made, taking into account the benefit of breast feeding to the child and the benefit of bupropion (Zyban<sup>®</sup>) to the woman. NRT, if acceptable, should be the treatment of choice for lactating women. This should be in combination with behavioural support to give all people who smoke the optimum chance of success of stopping smoking on every occasion. This is in accordance with NICE guidance and the Summary of Product Characteristics.

C3: It is unknown whether varenicline (Champix<sup>®</sup>) is excreted in human breast milk, but animal studies suggest that it is and it should be used with caution by women who are lactating. A decision on whether or not to continue breastfeeding with concomitant use of varenicline (Champix<sup>®</sup>) should be made, taking into account the benefit of breastfeeding to the child and the benefit of varenicline (Champix<sup>®</sup>) to the woman. NRT, if acceptable, should be the treatment of choice for lactating women. This should be in combination with behavioural support to give all people who smoke the optimum chance of success of stopping smoking on every occasion. This is in accordance with NICE guidance and the Summary of Product Characteristics.

C4: NRT can be prescribed or supplied to pregnant women. Pregnant women who have been unable to stop smoking without NRT and who wish to use NRT should be able to access it as easily as possible. This is in accordance with NICE guidance.

C5: NRT can be prescribed or supplied to lactating women (lactation is not a contraindication to the use of NRT).

C6: Intermittent medications, such as inhalator, gum, lozenges or spray, should be recommended to pregnant or lactating women in preference to patches (to allow maximum time between NRT use and breast feeding in the latter group), but 16 hour patches should be available to those who cannot tolerate oral NRT products. Patches should be removed at night (this is in accordance with NICE guidance).

C7: Combination NRT i.e. two NRT products, should be offered, if appropriate, as this is more effective than a single product (usually a combination of transdermal patches with a fast-acting product such as an inhalator, gum, lozenges or spray) to all pregnant women who smoke and have been unable to stop smoking without NRT.

C8: Combination NRT i.e. two NRT products, should be offered, if appropriate, as this is more effective than a single product.

C9: Prescriptions for NRT for pregnant or lactating women should not exceed **a maximum of 2 weeks at a time** (unless in extenuating circumstances) and for a maximum total of 12 weeks. Hertfordshire Public Health Service will only fund a maximum of 12 weeks of treatment. . If the patient wants to continue to use NRT after this time, then this should be self-funded. This is in accordance with Hertfordshire County Council's service specification for the delivery of stop smoking services (see Appendix 3).

C10: Advice regarding the risks and benefits of using NRT in pregnancy or while lactating should be given by a trained advisor who has attended Hertfordshire Health Improvement Service (HHIS) Smoking Cessation in Pregnancy training (3 hour session). This is in accordance with NICE guidance.

C11: Pregnant or lactating women can be provided with NRT directly through a community pharmacy without a consultation with their GP.

C12: The use of e-cigarettes (self-funded) should not be discouraged in pregnant or lactating women.

- C13: When recommending NRT for pregnant or lactating women, HHIS advisors and GP surgery advisors must complete a Letter of Recommendation (LoR) to supply NRT, which can be taken to a pharmacy for dispensing. The dispensing pharmacist should be made aware that the woman is pregnant.
- C14: Pharmacy advisors can dispense NRT to pregnant or lactating women against their own LoR. The dispensing pharmacist should be made aware that the woman is pregnant.
- C15: Information on each quit attempt, including quit date and type of medication used, should be recorded in the hand held maternity notes of all pregnant women who are planning to stop smoking as well as on QuitManager.

*NOTE: please also see section F (prescribing and dispensing recommendations relating to all population groups).*

## **Section D: prescribing and dispensing for young people (under 18 years)**

D1: **DO NOT** prescribe or supply varenicline (Champix<sup>®</sup>) or bupropion (Zyban<sup>®</sup>) to people below the age of 18 years of age (contraindicated). This is in accordance with NICE guidance and the Summary of Product Characteristics.

- D2: NRT is licensed for use in young people aged 12 years and over. This should be in combination with behavioural support and supervision to give all young people who smoke the optimum chance of success of stopping smoking on every occasion. This is in accordance with NICE guidance. Advisors should ensure that all 12-16 year olds seeking medication and support can demonstrate competence in line with the Fraser guidelines.
- D3: Young people aged under 12 years may be prescribed NRT off-licence at the discretion of a GP or registered prescriber only.
- D4: Combination NRT i.e. two NRT products, should be recommended if appropriate as this is more effective than a single product. In Hertfordshire, only NRT patches may be supplied as part of a stop smoking service. Individuals (unless pregnant) should be encouraged to self-fund a second nicotine containing product. Individuals who have a serious reaction to patches (local skin reaction is normal) or skin disorder may be supplied with an intermittent NRT product.
- D5: Prescriptions for NRT should not exceed **a maximum of 2 weeks at a time** (unless in extenuating circumstances) and for a maximum total of 12 weeks. Hertfordshire Public Health Service will only fund a maximum of 12 weeks of treatment. If the patient wants to continue to use NRT after this time, then this should be self-funded. This is in accordance with the Hertfordshire County Council's service specification for the delivery of stop smoking services (see Appendix 3).
- D6: E-cigarettes (self-funded) should not be discouraged in people aged under 18 years of age who would otherwise be smoking.

*NOTE: please also see section F (prescribing and dispensing recommendations relating to all population groups).*

## **Section E: prescribing and dispensing for adults with a diagnosed mental health condition**

- E1: People with a diagnosed mental health condition should be offered intensive behavioural support to stop smoking and referred to Hertfordshire Stop Smoking Service. This is in accordance with NICE guidance.
- E2: Varenicline (if there are no contra-indications) and NRT should be offered as equal first line treatments.
- E3: Bupropion (if there are no contraindications) may be used with caution in people with mental health conditions.

- E4: Higher doses of NRT may be required by people with mental health conditions as they are usually more nicotine dependent than the general population. In Hertfordshire, individuals with a diagnosed mental health condition should be referred to Hertfordshire Health Improvement Service for more intensive support and higher doses of NRT if appropriate.
- E5: Combination NRT i.e. two NRT products should be recommended if appropriate and this is more effective than a single NRT product.

In Hertfordshire, only NRT patches may be supplied as part of a stop smoking service. Individuals (unless pregnant) should be encouraged to self-fund a second nicotine product (or use varenicline if clinically appropriate). Individuals who have a serious reaction to patches (local skin reaction is normal) or skin disorder may be supplied with an intermittent NRT product. Individuals with a diagnosed mental health condition should be referred to Hertfordshire Health Improvement Service for more intensive support and higher doses of NRT if appropriate.

- E6: Prescriptions for NRT, varenicline (Champix<sup>®</sup>) or bupropion (Zyban<sup>®</sup>) should not exceed a **maximum of 2 weeks at a time** (unless in extenuating circumstances) and for a maximum total of 12 weeks. Hertfordshire Public Health Service will only fund a maximum of 12 weeks of treatment. . If the patient wants to continue to use NRT after this time, then this should be self-funded. This is in accordance with the Hertfordshire County Council's service specification for the delivery of stop smoking services (see Appendix 3).
- E7: E-cigarettes should be supported and encouraged in people with mental health conditions to reduce smoking or stop smoking altogether (self-funded) and may be used in combination with NRT (single or combination).
- E8: Be aware of nicotine withdrawal symptoms, in particular, the possible emergence of significant depressive symptoms in people attempting to stop smoking, with or without medication.
- E9: Ensure people who use medicines that are affected by smoking (or stopping smoking) are monitored, and the dosage adjusted if appropriate. Medicines that are affected include clozapine, olanzapine, warfarin, chlorpromazine, methadone, theophylline and insulin. This is not an exhaustive list and further information can be found here: [http://www.oxfordhealthformulary.nhs.uk/docs/Which%20medicines%20need%20dose%20adjustment%](http://www.oxfordhealthformulary.nhs.uk/docs/Which%20medicines%20need%20dose%20adjustment%20) (UK Medicines Information 2012).

*NOTE: please also see section F (prescribing and dispensing recommendations relating to all population groups).*

## **Section F: prescribing and dispensing recommendations relating to all population groups**

- F1: When deciding which medicines to use and in which order, discuss the options with the person and take into account:
- Whether a referral to a stop smoking service in Hertfordshire has been made
  - Contraindications, cautions and the potential for adverse events
  - The person's personal preferences
  - The individual's commitment to receiving counselling or support
  - The likelihood that the person will follow the course of treatment
  - The person's previous experience of attempting to quit smoking and medicines used
- This is in accordance with NICE guidance.
- F2: Do not put stop smoking medicines on repeat prescription.
- F3: If the person continues to smoke, do not prescribe any medications for more than 2 weeks after the set quit date without consultation with Hertfordshire Stop Smoking Service. This is in accordance with NICE guidance.

- F4: All medicines may be recommended or prescribed for a maximum of 12 weeks for individuals who have stopped smoking. The full summary of product characteristics (SPCs) for the above products can be found on the electronic medicines compendium website: <http://emc.medicines.org.uk>.
- F5: All medicines may be prescribed or recommended for more than one attempt to stop smoking. There is no definitive period between treatment episodes, and provided the person remains motivated, they should be given a new course of medication. This should be recorded on QuitManager, or alternative database approved by Hertfordshire County Council, as a new episode of treatment.
- F6: If an individual relapses and does not wish to begin a new treatment episode, no further medicines should be given until such time they are motivated to stop smoking again. This is in accordance with NICE guidance. Refer to [Hertfordshire's guidance on tobacco harm reduction](#) to support those who are not ready to quit smoking.
- F7: Individuals who relapse may purchase e-cigarettes or NRT to reduce the amount of tobacco they smoke.
- F8: Access to medications should be as straightforward and as soon as possible once the quit date has been agreed.
- F9: Supporting information on the relative effectiveness of each medication should be provided to the person planning to stop smoking.
- F10: Encourage users of e-cigarettes (self-funded) to receive behavioural support to help them to stop smoking.
- F11: Be aware of all nicotine withdrawal symptoms, and in particular, the possible emergence of significant depressive symptoms in people attempting to stop smoking, with or without medication, and advise accordingly.

## Evidence to support recommendations

Rec	Supporting Evidence
A1	This recommendation is in line with recommendation 4 of public health guidance 10 (NICE 2013)
A2	This recommendation is in line with the local interim guidance statement (East of England Priorities Advisory Committee 2016)
B1	<ul style="list-style-type: none"> <li>This recommendation is in line with technology appraisal guidance 123 (NICE 2007)</li> <li>This recommendation is in line with recommendation 4 of public health guidance 10 (NICE 2013)</li> <li>This recommendation is supported by quality statement 3 in Quality Standard 43 (NICE 2013a)</li> <li>This recommendation is supported by evidence in a National Centre for Smoking Cessation and Training briefing on varenicline (National Centre for Smoking Cessation and Training 2013)</li> </ul>
B2	<ul style="list-style-type: none"> <li>This recommendation is in line with recommendation 4 of public health guidance 10 (NICE 2013)</li> <li>This recommendation is supported by evidence in a briefing paper by the National Centre for Smoking Cessation and Training on Combination NRT (National Centre for Smoking Cessation and Training 2013a)</li> </ul>
B3	<ul style="list-style-type: none"> <li>This recommendation is supported by a briefing paper by the National Centre for Smoking Cessation and Training on e-cigarettes (National Centre for Smoking Cessation and Training 2016)</li> <li>This recommendation is in line with Hertfordshire County Council's policy on electronic cigarettes: Tobacco harm reduction: A policy statement on the use of e-cigarettes</li> </ul>
B4	<ul style="list-style-type: none"> <li>This recommendation is in line with recommendation 4 of public health guidance 10 (NICE 2013)</li> <li>This recommendation is supported by quality statement 4 in Quality Standard 43 (NICE 2013a)</li> <li>This recommendation is in line with the Service Specification for the delivery of Stop Smoking Services commissioned by Hertfordshire Public Health Service (see Appendix 3)</li> </ul>
B5	This recommendation is informed by evidence in the varenicline (Champix®) SPC (Pfizer, 2016)
B6	This recommendation is supported by a UKMi Question and Answer Paper 136.4 (UK Medicines

Rec	Supporting Evidence
C1	<ul style="list-style-type: none"> <li>• This recommendation is in line with recommendation 5 of public health guidance 26 (NICE 2010)</li> <li>• This recommendation is in line with recommendation 4 of public health guidance 10 (NICE 2013)</li> <li>• This recommendation is informed by evidence in the varenicline (Champix®) SPC (Pfizer, 2016)</li> <li>• This recommendation is informed by evidence in the bupropion (Zyban®) SPC (GlaxoSmithKline UK 2016)</li> </ul>
C2	<ul style="list-style-type: none"> <li>• This recommendation is supported by quality statement 3 in Quality Standard 43 (NICE 2013a)</li> <li>• This recommendation is informed by evidence in the bupropion (Zyban®) SPC (GlaxoSmithKline UK 2016)</li> <li>• This recommendation is informed by evidence in the various SPCs for NRT products e.g. Nicorette 15mg inhalator ( McNeil Products Ltd, 2016)</li> </ul>
C3	<ul style="list-style-type: none"> <li>• This recommendation is supported by quality statement 3 in Quality Standard 43 (NICE 2013a)</li> <li>• This recommendation is informed by evidence in the varenicline (Champix®) SPC (Pfizer, 2016)</li> <li>• This recommendation is informed by evidence in the various SPCs for NRT products e.g. Nicorette 15mg inhalator ( McNeil Products Ltd, 2016)</li> </ul>
C4	This recommendation is in line with recommendation 5 of public health guidance 26 (NICE 2010)
C5	This recommendation is informed by evidence in the various SPCs for NRT products e.g. Nicorette 15mg inhalator ( McNeil Products Ltd, 2016)
C6	<ul style="list-style-type: none"> <li>• This recommendation is in line with recommendation 5 of public health guidance 26 (NICE 2010)</li> <li>• This recommendation is in line with recommendations 8 and 9 of public health guidance 10 (NICE 2013)</li> <li>• This recommendation is informed by evidence in the various SPCs for NRT products e.g. Nicorette 15mg inhalator ( McNeil Products Ltd, 2016)</li> </ul>
C7	<ul style="list-style-type: none"> <li>• This recommendation is in line with technology appraisal guidance 123 (NICE 2007)</li> <li>• This recommendation is in line with recommendation 4 of public health guidance 10 (NICE 2013)</li> <li>• This recommendation is supported by quality statement 3 in Quality Standard 43 (NICE 2013a)</li> <li>• This recommendation is supported by evince in a National Centre for Smoking Cessation and Training briefing on varenicline (National Centre for Smoking Cessation and Training 2013)</li> <li>• This recommendation is supported by a report from ASH on smoking Cessation in Pregnancy (ASH 2015)</li> </ul>
C8	<ul style="list-style-type: none"> <li>• This recommendation is in line with technology appraisal guidance 123 (NICE 2007)</li> <li>• This recommendation is in line with recommendation 4 of public health guidance 10 (NICE 2013)</li> <li>• This recommendation is supported by quality statement 3 in Quality Standard 43 (NICE 2013a)</li> <li>• This recommendation is supported by evince in a National Centre for Smoking Cessation and Training briefing on varenicline (National Centre for Smoking Cessation and Training 2013)</li> <li>• This recommendation is supported by a report from ASH on smoking Cessation in Pregnancy (ASH 2015)</li> </ul>
C9	<ul style="list-style-type: none"> <li>• This recommendation is in line with recommendation 4 of public health guidance 10 (NICE 2013)</li> <li>• This recommendation is supported by quality statement 4 in Quality Standard 43 (NICE 2013a)</li> <li>• This recommendation is in line with the Service Specification for the delivery of Stop Smoking Services commissioned by Hertfordshire Public Health Service (see Appendix 3)</li> </ul>
C10	<ul style="list-style-type: none"> <li>• This recommendation is in line with recommendation 8 of public health guidance 26 (NICE 2010)</li> <li>• This recommendation is in line with recommendation 12 of public health guidance 10 (NICE 2013)</li> </ul>
C11	This recommendation is in line with the Service Specification for the delivery of Stop Smoking Services commissioned by Hertfordshire Public Health Service (see Appendix 3)
C12	<ul style="list-style-type: none"> <li>• This recommendation is supported by a briefing paper by the National Centre for Smoking Cessation and Training on e-cigarettes (National Centre for Smoking Cessation and Training 2016)</li> <li>• This recommendation is supported by a Public Health England evidence report on e-cigarettes (Public Health England 2015)</li> </ul>
C13	This recommendation is in line with the Service Specification for the delivery of Stop Smoking Services commissioned by Hertfordshire Public Health Service (see Appendix 3)
C14	This recommendation is in line with the Service Specification for the delivery of Stop Smoking Services commissioned by Hertfordshire Public Health Service (see Appendix 3)
C15	This recommendation is in line with recommendation 4 of public health guidance 26 (NICE 2010)
D1	<ul style="list-style-type: none"> <li>• This recommendation is in line with recommendation 4 of public health guidance 10 (NICE 2013)</li> <li>• This recommendation is informed by evidence in the varenicline (Champix®) SPC (Pfizer, 2016)</li> </ul>

Rec	Supporting Evidence
	<ul style="list-style-type: none"> <li>This recommendation is informed by evidence in the bupropion (Zyban®) SPC (GlaxoSmithKline UK 2016)</li> </ul>
D2	<ul style="list-style-type: none"> <li>This recommendation is in line with recommendation 10 of public health guidance 10 (NICE 2013)</li> <li>This recommendation is supported by quality statement 3 in Quality Standard 43 (NICE 2013a)</li> <li>This recommendation is informed by evidence in the various SPCs for NRT products e.g. Nicorette 15mg inhalator (McNeil Products Ltd, 2016)</li> </ul>
D3	This recommendation is in line with good clinical practice and in consideration of young people addicted to tobacco
D4	<ul style="list-style-type: none"> <li>This recommendation is in line with technology appraisal guidance 123 (NICE 2007)</li> <li>This recommendation is in line with recommendation 4 of public health guidance 10 (NICE 2013)</li> <li>This recommendation is supported by quality statement 3 in Quality Standard 43 (NICE 2013a)</li> <li>This recommendation is supported by evidence in a National Centre for Smoking Cessation and Training briefing on varenicline (National Centre for Smoking Cessation and Training 2013)</li> </ul>
D5	<ul style="list-style-type: none"> <li>This recommendation is in line with recommendation 4 of public health guidance 10 (NICE 2013)</li> <li>This recommendation is supported by quality statement 4 in Quality Standard 43 (NICE 2013a)</li> <li>This recommendation is in line with the Service Specification for the delivery of Stop Smoking Services commissioned by Hertfordshire Public Health Service (see Appendix 3)</li> </ul>
D6	<ul style="list-style-type: none"> <li>Note: e-cigarettes are not licensed or regulated for people under 18.</li> <li>This recommendation is supported by a Public Health England evidence report on e-cigarettes (Public Health England 2015)</li> </ul>
E1	<ul style="list-style-type: none"> <li>This recommendation is in line with technology appraisal guidance 123 (NICE 2007)</li> <li>This recommendation is supported by quality statement 3 in Quality Standard 43 (NICE 2013a)</li> </ul>
E2	This recommendation is supported by evidence in a National Centre for Smoking Cessation and Training briefing on varenicline (National Centre for Smoking Cessation and Training 2013)
E3	This recommendation is informed by evidence in the bupropion (Zyban®) SPC (GlaxoSmithKline UK 2016)
E4	This recommendation is supported by an RCP and RCPsych report on smoking and mental health (Royal College of Physicians and Royal College of Psychiatrists, 2013)
E5	<ul style="list-style-type: none"> <li>This recommendation is in line with recommendation 4 of public health guidance 10 (NICE 2013)</li> <li>This recommendation is supported evidence in a briefing paper by the National Centre for Smoking Cessation and Training on Combination NRT (National Centre for Smoking Cessation and Training 2013a)</li> </ul>
E6	<ul style="list-style-type: none"> <li>This recommendation is in line with recommendation 4 of public health guidance 10 (NICE 2013)</li> <li>This recommendation is supported by quality statement 4 in Quality Standard 43 (NICE 2013a)</li> <li>This recommendation is in line with the Service Specification for the delivery of Stop Smoking Services commissioned by Hertfordshire Public Health Service (see Appendix 3)</li> </ul>
E7	This recommendation is supported by an RCP report on electronic cigarettes (Royal College of Physicians, 2016)
E8	This recommendation is informed by evidence in the varenicline (Champix®) SPC (Pfizer, 2016)
E9	This recommendation is informed by evidence in the varenicline (Champix®) SPC (Pfizer, 2016)
F1	This recommendation is in line with recommendation 4 of public health guidance 10 (NICE 2013)
F2	This recommendation is to ensure that there is adherence to recommendation B4
F3	<ul style="list-style-type: none"> <li>This recommendation is in line with recommendation 5 of public health guidance 26 (NICE 2010)</li> <li>This recommendation is in line with recommendation 4 of public health guidance 10 (NICE 2013)</li> </ul>
F4	This recommendation is supported by quality statement 4 in Quality Standard 43 (NICE 2013a)
F5	This is in line with the Service Specification for the delivery of Stop Smoking Services commissioned by Hertfordshire Public Health Service (see Appendix 3)
F6	<ul style="list-style-type: none"> <li>This recommendation is in line with recommendation 5 of public health guidance 26 (NICE 2010)</li> <li>Also see Hertfordshire Guidance on Tobacco Harm Reduction (Hertfordshire County Council 2015)</li> </ul>
F7	This recommendation is supported by Hertfordshire Guidance on Tobacco Harm Reduction (Hertfordshire County Council 2015)
F8	This recommendation is in line with the Service Specification for the delivery of Stop Smoking Services commissioned by Hertfordshire Public Health Service (see Appendix 3)
F9	This is in line with the Service Specification for the delivery of Stop Smoking Services commissioned by Hertfordshire Public Health Service (see Appendix 3)
F10	<ul style="list-style-type: none"> <li>This recommendation is supported by a briefing paper by the National Centre for Smoking</li> </ul>

Rec	Supporting Evidence
	Cessation and Training on e-cigarettes (National Centre for Smoking Cessation and Training 2016) <ul style="list-style-type: none"> <li>This recommendation is supported by a Public Health England evidence report on e-cigarettes (Public Health England (2015))</li> </ul>
F11	This recommendation is informed by evidence in the varenicline (Champix <sup>®</sup> ) SPC (Pfizer, 2016)

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# Appendix 1: Medications available to be used under these guidelines

The following is for guidance only, please refer to the BNF or the Summary of Product Characteristics (SPCs) for full prescribing information including contraindications, cautions and drug interactions:  
<http://emc.medicines.org.uk>

## Nicotine Replacement Therapy

NRT can be used as single or combination therapy

### Patches

Nicorette Invisipatch (16 hour) 10mg, 15mg, 25mg  
Pharmacy own label Translucent Patch (16 hour) 10mg, 15mg, 25mg  
Nicotinell TTS10, TTS20, TTS30  
NiQuitin Clear or NiQuitin Transdermal Patch (24 hour) 7mg, 14mg, 21mg  
Pharmacy own label Transdermal Patch (24 hour) 7mg, 14mg, 21mg

### Lozenges

Nicorette Cools 2mg, 4mg  
Nicorette Fruit Fusion, 4mg, 6mg  
Nicorette Icy White, 2mg, 4mg  
Nicotinell Mint, 1mg, 2mg  
NiQuitin Minis, 1.5mg, 4mg (all flavours)  
NiQuitin Mint Lozenges, 4mg  
Pharmacy own label Lozenges, 1mg, 2mg

### Sublingual tablets

Nicorette Microtabs, 2mg  
Pharmacy own label Microtabs, 2mg

### Chewing Gum

Nicorette Gum, 2mg, 4mg, 6mg (all flavours)  
Nicotinell Gum, 2mg, 4mg (all flavours)  
NiQuitin Mint Medicated Gum, 2mg, 4mg  
Pharmacy own label Gum 2mg, 4mg

### Inhalator

Nicorette Inhalator, 15mg  
Pharmacy own label Inhalator, 15mg

### Nasal Spray

Nicorette Nasal Spray, 10mg/ml  
Pharmacy own label Nasal Spray, 10mg/ml

### Mouth Spray

Nicorette QuickMist, 1mg/spray

### Oral Strips

NiQuitin Oral Strip, 2.5mg

**Please note: ONLY NRT PATCHES WILL BE REIMBURSED. Intermittent NRT products will ONLY be reimbursed if supplied in line with this guidance. Duo packs of NRT and lozenges will not be reimbursed as they are more expensive than separate packs of each.**

## **Varenicline (Champix®)**

Starter Pack: 0.5mg & 1mg oral tablets

Recommended dose: 1mg oral tablets twice daily following a 1-week titration (Day 1-3: take one 0.5mg tablet once daily, Day 4-7: take one 0.5 mg tablet once in the morning and once in the evening, at about the same time each day; Day 8 - end of treatment: take one 1mg tablet twice daily, at about the same time each day) for 12 weeks' duration. A planned quit date should be set and patients should begin the course 1-2 weeks before the set quit date. Patients who cannot tolerate the side effects of varenicline (principally nausea) may have the dose lowered temporarily or permanently to 0.5 mg twice daily for the 12 weeks' duration.

### **Effects of Smoking Cessation**

A large randomised trial showed cessation rates in people with major depressive disorders were similar to those in the general population. Psychiatric scales showed no differences between the varenicline and placebo groups and no overall worsening of depression, or other psychiatric symptoms, during the study in either treatment group (Evaluating Adverse Events in a Global Smoking Cessation Study (EAGLES study)).

Cigarette smoking increases the metabolism of some medicines by stimulating the hepatic enzyme CYP1A2 and physiological changes resulting from smoking cessation, with or without treatment with varenicline, may alter the pharmacokinetics of some medicinal products for which dose adjustment may be necessary (examples include: clozapine, olanzapine, warfarin, chlorpromazine, methadone, theophylline and insulin). This list is not exhaustive and further clarification using the relevant reference sources, cross referencing and the client's current medication profile should be made by the professional advising the client about stopping smoking.

Varenicline has no known clinically meaningful interactions with other medications and is no longer a black triangle medicine.

### **Contraindications:**

- Pregnancy
- Not recommended for patients under 18 years of age
- End-stage renal disease
- Hypersensitivity to the active substance or to any of the excipients listed in the summary of product characteristics (SPCs)

### **Cautions:**

- Clinicians should be aware of the possible emergence of serious neuropsychiatric symptoms in patients attempting to quit smoking with or without treatment. Depressed mood, rarely including suicidal ideation and suicide attempt, may be a symptom of nicotine withdrawal. There have been post marketing reports of changes in behaviour or thinking, anxiety, psychosis, mood swings, aggressive behaviour, depression, suicidal ideation and behaviour and suicide attempts.
- History of psychiatric disorders: smoking cessation, with or without pharmacotherapy, has been associated with exacerbation of underlying psychiatric illness (e.g. depression). In a smoking cessation clinical trial, neuropsychiatric adverse events were reported more frequently in patients with a history of psychiatric disorders compared to those without a history of psychiatric disorders, regardless of treatment. Care should be taken with patients with a history of psychiatric illness and patients should be advised accordingly. If serious neuropsychiatric symptoms occur whilst on varenicline treatment, patients should discontinue varenicline immediately and contact a healthcare professional for re-evaluation of treatment.
- The use of varenicline in patients with or without a history of psychiatric disorder has not been associated with an increased risk of serious neuropsychiatric adverse events compared with placebo (Evaluating Adverse Events in a Global Smoking Cessation Study (EAGLES study)).
- Alcohol: there are limited clinical data on any potential interaction between alcohol and varenicline. There have been post marketing reports of increased intoxicating effects of alcohol in patients treated with varenicline. A causal relationship between these events and varenicline use has not been established.
- Cimetidine: Co-administration of cimetidine, with varenicline increased the systemic exposure of varenicline by 29% due to a reduction in varenicline renal clearance. No dosage adjustment is recommended based on concomitant cimetidine administration in subjects with normal renal function or in patients with mild to moderate renal impairment. In patients with severe renal impairment, the concomitant use of cimetidine and varenicline should be avoided.
- Varenicline may have minor or moderate influence on the ability to drive and use machines. Varenicline may cause dizziness and somnolence and therefore may influence the ability to drive and use machines. Patients are advised not to drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether this medicinal product affects their ability to perform these activities.
- Cardiovascular events: Patients taking varenicline should be instructed to notify their doctor of new or worsening cardiovascular symptoms and to seek immediate medical attention if they experience signs and symptoms of myocardial infarction or stroke.

- Use with caution in patients with a history of seizures or other conditions which potentially lower the seizure threshold.
- Treatment discontinuation: at the end of treatment, discontinuation of varenicline was associated with an increase in irritability, urge to smoke, depression, and/or insomnia in up to 3% of patients. The prescriber should inform the patient accordingly and discuss or consider the need for dose tapering.
- Breastfeeding: It is unknown whether varenicline is excreted in human breast milk. Animal studies suggest that varenicline is excreted in breast milk. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with varenicline should be made taking into account the benefit of breastfeeding to the child and the benefit of varenicline therapy to the woman.
- Hypersensitivity reactions: post-marketing reports of hypersensitivity reactions including angioedema in patients treated with varenicline. Clinical signs included swelling of the face, mouth (tongue, lips, and gums), neck (throat and larynx) and extremities. There were rare reports of life-threatening angioedema requiring urgent medical attention due to respiratory compromise. Patients experiencing these symptoms should discontinue treatment with varenicline and contact a health care provider immediately.
- Cutaneous reactions: post-marketing reports of rare but severe cutaneous reactions, including Stevens-Johnson Syndrome and Erythema Multiforme in patients using varenicline. As these skin reactions can be life threatening, patients should discontinue treatment at the first sign of rash or skin reaction and contact a healthcare provider immediately.

### **Bupropion (Zyban®)**

150mg oral tablets. The initial dose is 150mg taken daily for 6 days increasing on day 7 to 150mg twice daily. There should be an interval of 8 hours between successive doses. A set quit date is planned, preferably during the second week of treatment.

#### **Contraindications:**

- Patients with current seizure disorder or history of seizures, CNS (central nervous system) tumour, patients experiencing abrupt withdrawal from alcohol or any medication known to be associated with risk of seizures on withdrawal e.g. benzodiazepines.
- Current or previous diagnosis of bulimia or anorexia nervosa.
- Bipolar disorder (may precipitate a manic episode during the depressed phase of their illness).
- Severe hepatic cirrhosis.
- Pregnancy.
- Patients under 18 years of age.
- Concomitant use of MAOIs. At least 14 days should elapse between discontinuation of irreversible MAOIs and initiation of treatment with Zyban. For reversible MAOIs, a 24 hour period is sufficient.
- Patients with hypersensitivity to bupropion or any of the excipients.
- Bupropion should not be administered to patients being treated with any other medicinal product containing bupropion as the incidence of seizures is dose dependent and to avoid overdosage.

#### **Cautions:**

- Renal or mild to moderate hepatic impairment. The maximum recommended dose is 150mg daily.
- Bupropion should be used with caution in patients with renal insufficiency. The recommended dose in these patients is 150mg daily.
- Increase in blood pressure has been reported - monitor BP before and during treatment, especially in patients with pre-existing hypertension.
- History of psychiatric illness. Neuropsychiatric reactions, in particular, psychotic and manic symptomatology have been reported mainly in patients with a known history of psychiatric illness.
- Older people. The maximum recommended dose is 150mg daily.
- Predisposing risk factors which lower the seizure threshold e.g. certain other medicinal products; history of head trauma; alcohol abuse; tablet or insulin controlled diabetes; stimulants or anorectic products.
- The consumption of alcohol during bupropion treatment should be minimised or avoided.
- Breastfeeding: bupropion and its metabolites are excreted in human breast milk. A decision on whether to abstain from breast-feeding or to abstain from therapy with bupropion should be made taking into account the benefit of breast-feeding to the newborn/infant and benefit of bupropion therapy to the mother.
- Although discontinuation reactions are not expected with bupropion, a tapering-off period may be considered.

#### **Interactions:**

Please see SPC at <http://emc.medicines.org.uk> for full list of interactions with other medicines.

## Appendix 2: E-cigarettes and other nicotine containing devices

Electronic cigarettes are devices that deliver nicotine by heating and vaporising a solution that typically contains nicotine, propylene glycol and/or glycerol and flavourings.

There are almost 3 million users of e-cigarettes in the UK and there is a growing body of evidence which shows they are much less harmful than smoking (estimated to be 95% safer than smoked tobacco). Further information may be found here: <https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update>

From 20 May 2016 e-cigarettes must meet the requirements of the European Union Tobacco Product Directive:

- If they contain less than 20mg nicotine, they are required to be regulated by the MHRA. These regulated products must not be advertised in any form, sold to people under 18 years or be advertised with any claims about health benefits.
- E-cigarettes containing 20mg or more nicotine must be licensed with the MHRA. Any E-cigarette licensed with the MHRA will be reviewed through standard processes for new medicines for effectiveness and cost effectiveness before any recommendations are made for its use in Hertfordshire.

## Appendix 3: Service specification algorithm

### FIRST CONTACT:

Service user presents for help to stop smoking at a local pharmacy, GP practice, Specialist Stop Smoking Service or alternative provider. If Service user wants to quit; explain service and expectation of weekly support for best chance of success; give Health Questionnaire, booklet on stopping smoking and make first appointment. Consider referral to specialist service if Service user is pregnant, has a mental health condition or complex needs, or has not quit successfully with your service x2 previously. Explain commitment is for at least 4 weeks following quit date. If Service User not ready to quit, give harm reduction advice, including advice on e-cigarettes.

### Medication:

**Some medication may reach toxic levels following smoking cessation or reduction. Please access**

<http://www.oxfordhealthformulary.nhs.uk/searchresults.asp?SearchVar=smoking&Submit=Search> for details of medicines which may need dose adjusting

### FIRST APPOINTMENT: Usually pre-quit (30 mins or 45 mins if pregnant)

Establish Service user relationship  
Note relevant medical history/medication from Health Questionnaire  
Assess smoking history and current dependency (Fagerstrom test)  
Assess motivation and confidence to quit  
CONSENT: complete consent on QuitManager  
Explain CO monitoring and record reading (use as motivational tool)  
Negotiate quit date and discuss planning for it  
Provide literature e.g. "It's so much easier since I quit."  
Discuss behaviour change/breaking the habit  
Discuss withdrawal symptoms and coping mechanisms  
Discuss all medication options approved by NICE, in line with local guidelines and patient choice. Facilitate supply, explain use, and complete clinical record.  
Complete additional Smoking in Pregnancy forms if required  
Make next appointment or follow up any DNAs  
Complete all mandatory fields on QuitManager

### NRT option:

Provide voucher (Letter of Recommendation) for NRT to take to pharmacy (maximum 2 weeks supply)

**Varenicline or bupropion option:** Advisor prescribes, recommends or supplies varenicline or bupropion within NICE guidance and Hertfordshire guidance: Stop smoking medication and the SPCs

### APPOINTMENTS 2, 3 and subsequent appointments (10-15 minutes on or shortly after quit date and each and every following week)

Assess progress so far - congratulate any constructive behaviour change/efforts  
Confirm quit date/set quit date  
Take CO reading to use as a motivator  
Monitor use of medication – ensure adequate use and monitor side effects (adjust dose or change medication if severe adverse effects)  
Ensure adequate medication until next appointment  
Complete clinic notes in QuitManager  
Discuss any lapses or barriers to quitting/difficulties to be overcome  
Discuss withdrawal symptoms and coping mechanisms

### FINAL APPOINTMENT: between 25 and 42 days after quit date (NHS reporting deadlines)

Assess progress so far - quit or not quit at this four-week follow-up appointment  
Congratulate success if appropriate and encourage staying stopped  
For those who haven't quit, suggest returning for another course when ready  
Complete CO reading (must be less than 10ppm to validate non-smoking status)  
Service user must be smoke free for the last 14 days of the 28 days since setting a quit date  
**Complete Quit Status on QuitManager for monitoring and payment purposes**  
Complete clinical record  
Identify risks to staying stopped and ensure patient empowered to access service in future without fear of failure if relapse occurs. Agree additional support for complex Service users or refer to HHIS

Ensure sufficient supply of NRT, varenicline or bupropion to complete full course of medication

For queries contact: Hertfordshire Health Improvement Service on 01442 453071 or email: [HealthImprovementService@hertfordshire.gov.uk](mailto:HealthImprovementService@hertfordshire.gov.uk)

## Abbreviations

<b>BNF</b>	British National Formulary
<b>CNS</b>	Central Nervous System
<b>GP</b>	General Practitioner
<b>HHIS</b>	Hertfordshire Health Improvement Service (formerly Hertfordshire Stop Smoking Service (HSS))
<b>LoR</b>	Letter of Recommendation to supply NRT by a community pharmacy
<b>MHRA</b>	Medicines and Healthcare Products Regulatory Agency
<b>MOAIs</b>	Mono-amine Oxidase Inhibitors (a range of anti-depressant medication)
<b>NCSCCT</b>	National Centre for Smoking Cessation and Training
<b>NICE</b>	National Institute for Health and Care Excellence
<b>NRT</b>	Nicotine Replacement Therapy
<b>SPCs</b>	Summary of Product Characteristic