Prescribing guidance in
Smoking Cessation
March 2011
The aim of this guidance is to update previous prescribing guidance (2007) ensuring that there is a consistent approach throughout Dumfries & Galloway to the prescribing and support given to patients who wish to stop smoking.

Evidence has shown that increasing the intensity of behavioural support, along with the use of pharmacotherapy, increases the likelihood of a successful quit. Smokers should always be encouraged to accept the most intensive support available to them. In Dumfries and Galloway, it is recommended that smokers are referred on for specialist support To The Smoking Matters Service or to Community Pharmacists providing a Smoking Cessation Service.

This guidance should be used by all prescribers when patients decline a referral on to specialist services.

For more information about this guidance please contact Trish Grierson trish.grierson@nhs.net Or Catherine Smith Catherine.smith4@nhs.net
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1. Introduction

This guidance provides users with the most up to date information taking account of the most recent publications i.e. “A guide to Smoking Cessation in Scotland” (2010) and relevant NICE guidelines.

Key points: -

• This guide should be used when a smoker has decided to stop smoking and pharmacotherapy should only be prescribed when a smoker has set a quit date

• Nicotine Replacement Therapy is effective in helping smokers to quit. The most recent systematic review of NRT studies concluded that it approximately doubles the chance of long-term abstinence compared to placebo

• All smokers should have the opportunity for structured support during their quit attempt including behavioural support along with pharmacotherapy

• All NRT products provide a clean source of nicotine in a different way from smoking

• There is no evidence for any difference in the efficacy of the various NRT products overall, therefore, it is generally agreed that choice of products can be guided by client preference. However, more dependent smokers may benefit more from a higher dose treatment or a faster acting treatment or a combination of NRT treatments

• Unaided quit attempts have a very low probability of success (1-2%). Therefore more intensive support has a greater likelihood of producing a successful outcome, as well as being more cost-effective

• NHS Dumfries & Galloway does not support “Cut down to Quit”

• For full details on doses, adverse effects, cautions and contra-indications of individual products refer to the Summary of Product Characteristics www.emc.medicines.org.uk or the most current British National Formulary (BNF)
# 2. Treatment Options

## First Choice - Nicotine Replacement Therapy (NRT)

For full details on doses adverse effects, cautions and contra-indications of individual products refer to the Summary of Product Characteristics [www.emc.medicines.org.uk](http://www.emc.medicines.org.uk) or the BNF.

<table>
<thead>
<tr>
<th>Product</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patch</strong></td>
<td>Easy to use</td>
<td>With 16 hour patch patient may have early morning craving</td>
</tr>
<tr>
<td>12 week course</td>
<td>Discreet</td>
<td>No oral satisfaction</td>
</tr>
<tr>
<td>16 Hour Patch</td>
<td>Breaks habits</td>
<td>Possible skin reaction – rotate the site of the patch to prevent irritation developing</td>
</tr>
<tr>
<td>(15mg, 10mg &amp; 5mg)</td>
<td>Supplies nicotine continuously throughout the day</td>
<td>24 hr patch can cause sleep disturbance</td>
</tr>
<tr>
<td>Invisi range (25mg, 15mg, 10mg)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Use one range of patches and do not interchange</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apply new patch once daily to a non-hairy area of skin. Take off before bedtime</td>
<td></td>
<td></td>
</tr>
<tr>
<td>24 Hour Patch</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(21mg, 14mg &amp; 7mg)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New patch once daily, keeping patch on all day and night changing next morning</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Lozenges</strong></td>
<td>Discreet, flexible and offers good dose control</td>
<td>Nicotine destroyed in stomach if product not used properly leading to heartburn or stomach irritation</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>1mg, 2mg 4mg</td>
<td>Easy to use</td>
<td>Stinging in mouth, hiccups and localized irritation can occur</td>
</tr>
<tr>
<td>Withdraw gradually after 3 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not licensed for under 18's</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SPC/BNF states withdraw after 3 months. However NHS Dumfries &amp; Galloway recommends 3 months maximum prescribing for a single quit attempt</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Microtabs</strong></th>
<th>Discreet, flexible and offers good dose control</th>
<th>The tablet must not be sucked, chewed or swallowed, as this will reduce the amount of nicotine absorbed</th>
</tr>
</thead>
<tbody>
<tr>
<td>2mg sublingual</td>
<td>Easy to use</td>
<td>Can cause stomach upset, stinging mouth, hiccups and localized irritation</td>
</tr>
<tr>
<td>The small tablet dissolves under the tongue</td>
<td>Side-effects minimal</td>
<td></td>
</tr>
<tr>
<td>SPC/BNF states withdraw after 3 months. However NHS Dumfries &amp; Galloway recommends 3 months maximum prescribing for a single quit attempt</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Inhalator</strong></th>
<th>Good for those who miss the behavioural habit of smoking</th>
<th>Some may feel self conscious using inhalator</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 week course</td>
<td>Easy to use</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Nasal Spray</strong></th>
<th>Fast acting for heavy smokers</th>
<th>Side effects – nasal irritation, eyes watering, coughing sneezing etc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bottle 1x10ml</td>
<td>Easy control of dose</td>
<td>Most addictive of the NRT products</td>
</tr>
<tr>
<td>12 week course</td>
<td></td>
<td>Some may feel self conscious using inhalator</td>
</tr>
<tr>
<td>Gum</td>
<td>Easy to use</td>
<td>Oral satisfaction</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>2mg and 4mg</td>
<td>Discreet</td>
<td>Available in a variety of flavours</td>
</tr>
<tr>
<td>“Chew/park/chew” technique should be used</td>
<td>Side-effects minimal</td>
<td></td>
</tr>
<tr>
<td>SPC/BNF states withdraw after 3 months. However NHS Dumfries &amp; Galloway recommends 3 months maximum prescribing for a single quit attempt</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liquorice flavoured gum is not to be used in pregnancy</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Combination NRT Therapy

Using a combination of NRT products (combination therapy) has been shown to have an advantage over using a single product. This approach can increase abstinence rates with no increase in side effects.

Therefore Combination Therapy should be considered under the following circumstances

- A smoker shows a high level of dependence (heavy nicotine dependent smoker)
  
  and

- Has previously found single forms of NRT inadequate
  
  and

- Is willing to participate in a stop smoking programme either with Smoking Matters or Community Pharmacists or in practices who can provide behavioural support along with pharmacotherapy

The combined use of nicotine patch (as the main product) along with a second intermittent product (such as gum, inhalator, lozenge or nasal spray) is recommended. The second product is to be used “only as required” for breakthrough cravings, and this should be reflected in the quantity prescribed i.e. smaller pack sizes.
Second Choice - Varenicline (Champix)
Prescription Only Medicine (POM)

Varenicline should be started 1 to 2 weeks before the date that the patient has set to stop smoking. The full treatment period should last for 12 weeks. There is limited evidence to suggest that those patients who are treated successfully may benefit from an additional 12 weeks of treatment. For full details see SPC/BNF

For full details on doses adverse effects, cautions and contra-indications of individual products refer to the Summary of Product Characteristics www.emc.medicines.org.uk or the BNF

<table>
<thead>
<tr>
<th>Normal Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>See Summary of Product Characteristics (SPC) for exceptions</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Days 1 to 3</th>
<th>0.5mg once daily</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days 4 to 7</td>
<td>0.5mg twice daily</td>
</tr>
<tr>
<td>Day 8 to end of treatment</td>
<td>1mg twice daily (Reduce to 0.5mg twice daily if not tolerated)</td>
</tr>
</tbody>
</table>

Cautions: Risk of relapse, irritability, depression, and insomnia on discontinuation (consider dose tapering on completion of 12-week course); history of psychiatric illness (may exacerbate underlying illness including depression)

MHRA/CHM advice
Patients should be advised to discontinue treatment and seek prompt medical advice if they develop agitation, depressed mood, or suicidal thoughts. Patients with a history of psychiatric illness should be monitored closely when taking Varenicline.

Side effects: The side effects associated with this drug should be discussed with the patient prior to treatment (See BNF or SPC). The most common side effects are gastro-intestinal disturbances, appetite changes, dry mouth, taste disturbance; headache, drowsiness, dizziness, sleeps disorders and abnormal dreams. Other less common side effects include anxiety, depression, aggression, irrational behaviour, psychosis, suicidal ideation
It is recommended that patients should avoid driving or operating machinery until they know whether varenicline affects their ability to carry out these tasks safely.

Varenicline is a ‘black triangle drug’ therefore all adverse drug reactions should be reported to the MHRA, not just serious events.

Varenicline should not be used in patients under 18 years old or during pregnancy/breastfeeding
Third Choice - Bupropion (Zyban)
Prescription Only Medicine (POM)

Bupropion should be started 1-2 weeks before target stop date. Treatment should continue for 7-9 weeks but should be discontinued if abstinence is not achieved by 7 weeks

For full details on doses, adverse effects, cautions and contra-indications of individual products refer to the Summary of Product Characteristics [www.emc.medicines.org.uk](http://www.emc.medicines.org.uk) or the BNF

<table>
<thead>
<tr>
<th></th>
<th>Normal Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days 1 to 6</td>
<td>150mg (one tablet) once daily</td>
</tr>
<tr>
<td>Days 7 to end of treatment</td>
<td>150mg twice daily (With 8 hours between doses)</td>
</tr>
</tbody>
</table>

**Cautions:** Elderly; predisposition to seizures (prescribe only if benefit clearly outweighs risk) including concomitant use of drugs that lower seizure threshold, alcohol abuse, history of head trauma, and diabetes; measure blood pressure before and during treatment

**Contra-indications:** Acute alcohol or benzodiazepine withdrawal; severe hepatic cirrhosis; CNS tumour; history of seizures, eating disorders, or bipolar disorder

**Interactions:** Bupropion has the potential to interact with other drugs

**Side Effects:** Side effects associated with this drug should be discussed with the patient prior to treatment (See BNF or SPC). The most common side effects are dry mouth, gastro-intestinal disturbances, taste disturbance; insomnia (reduced by avoiding dose at bedtime), tremor, impaired concentration, headache, dizziness, depression, agitation, anxiety; fever; rash, pruritus and sweating.
It is recommended that patients should avoid driving or operating machinery until they know whether Bupropion affects their ability to carry out these tasks safely.

**Bupropion should not be used in patients under 18yrs old or during pregnancy/breastfeeding**
3. Prescribing Flowchart

If a patient declines a referral on to specialist services it is recommended that prescribers follow this protocol

- Ask if your patient smokes and record this information

- Offer 2-weekly behavioural support in the practice for any patient receiving pharmacotherapy

- All products (excl. Varenicline) should be prescribed monthly with prescriptions being endorsed to be dispensed 2-weekly

- If Varenicline is prescribed the initial prescription should be for one starter pack only, and then review for monthly prescribing

- Products should be prescribed for a maximum of 3 months

- Do not place on patient repeat prescription list

- Record all relevant information and whether quit attempt has been successful/unsuccessful

- If this quit attempt is unsuccessful further prescribing should be offered through specialist support
4. High Risk Prescribing (Special Groups)

Summary of Points

In 2005 the Medicines and Healthcare Regulatory Authority undertook a review of the licensing arrangements for Nicotine Replacement Therapy.

The changes were

- All forms of NRT can be used for young people aged 12-17
- NRT can be used by pregnant women who smoke
- NRT can be used by breastfeeding mothers who smoke
- All forms of NRT can be used by people with cardiovascular disease

Pregnancy

Encouraging women to stop smoking as soon as a pregnancy is confirmed is important. In the third trimester nicotine has a haemodynamic effect (e.g. changes in foetal heart rate) which could affect the foetus close to delivery, therefore early intervention is extremely valuable.

It is requested that all pregnant women are referred on for specialist support to Smoking Matters.

When referring patients to Smoking Matters a clinical judgement by a GP or an approved prescriber is required before any pharmacotherapy can be provided.

The following protocol will be followed by Smoking Matters:

- Discuss Risks/Benefits assessment sheet (see appendix 2)
- 1st recommendation – Behavioural support only (No NRT)
- 2nd recommendation - NRT oral products (No Liquorice gum)
- 3rd recommendation - continuous use NRT product – only 16-hour patch

*Neither Varenicline or Bupropion should be used in pregnancy*
Breastfeeding

NRT may be recommended for breastfeeding women. If a breastfeeding woman expresses a wish to receive NRT professional judgement should be used. Any risk is likely to be small in comparison with the amount of nicotine from cigarettes and the smokefree environment will also outweigh any risk.

Using intermittent NRT may minimise the amount of nicotine in breast milk as the time between administration of NRT and feeding can be timed to ensure levels of NRT are at their lowest level.

_Always refer to SPC or BNF for full product information._

_Neither Varenicline or Bupropion should be used by breastfeeding women_

Patients with heart disease

Stopping smoking is important for those with heart disease (and other diseases such as respiratory).

If the patient declines a referral on to specialist services then a health professional should make a professional judgment about the benefits of stopping smoking against any risks there may be with using NRT (Varenicline or Bupropion). These patients will require intensive support and close monitoring to ensure a successful quit attempt.

In stable medical conditions NRT, Varenicline or Bupropion may be offered subject to a clinical judgement being made and providing the smoker is fully compliant with a stop smoking programme.

In unstable conditions NRT, Varenicline or Bupropion may be offered subject to a clinical judgement being made, a risk/benefit assessment has been made and the smoker is fully compliant with a stop smoking programme.

- Discuss Risks/benefits with the smoker
- 1st recommendation –Behavioural support only (No NRT)
- 2nd recommendation -NRT oral products
- 3rd recommendation- continuous use NRT products (only 16-hour patch) or Varenicline or Bupropion
Smokers who have diabetes

Smokers who have diabetes have a considerably increased risk of developing cardiovascular disease and other related complications. Ongoing smoking adds to this risk therefore it is important that diabetic patients are encouraged to stop smoking to minimise the risk of further complications.

If the patient declines a referral on to specialist services then a health professional should make a professional judgment about the benefits of stopping smoking against any risks there may be with using NRT (or Varenicline). These patients will require intensive support and close monitoring to ensure a successful quit attempt.

Always refer to SPC or BNF for full product information

Varenicline can be used subject to cautions

Blood sugar should be monitored more closely when someone is trying to stop smoking, since both stopping smoking and the use of NRT affect insulin metabolism.

It is important that smoking status of diabetic patients is recorded and patients should be encouraged to discuss their quit attempts with their diabetic team, regardless of what support they decide to use.

12-18 year olds

NRT can be used by adolescents, always refer to SPC or BNF for full product information

- Ensure compliance to behavioural support if prescribing
- Lozenges are not licensed for use in this age group
- Do not prescribe large quantities of a product to allow close monitoring of compliance

Neither Varenicline or Bupropion should be used by young people under 18
5. Secondary care (this includes prescribing for acute mental health patients in hospital)

All in-patients who are as recorded as a smoker and who have expressed a desire to stop smoking or need symptomatic relief while in hospital, follow this protocol:

- 1st choice treatment 16-hour patch ensuring this is recorded and monitored and removed overnight

- 2nd choice treatments - Inhalator 10mg cartridge, Microtabs 2mg, Gum 2mg & 4mg

It is the responsibility of the prescriber to ensure that NRT is appropriate for the specific patient and to prescribe accordingly on the in-patient notes. Requests should be made to pharmacy in the usual format.

*Always refer to SPC or BNF for full product information*

*Varenicline or Bupropion are not included within the Secondary Care prescribing protocol*

Dependent on a successful quit attempt, on discharge a patient can be prescribed a further 7 days treatment of NRT. An immediate referral should be made to Smoking Matters to ensure continued support of the quit attempt when the patient returns home.

*Phone Smoking Matters- 0845 602 6861 or Email dg.smokingmatters@nhs.net*
References

1. The UK Medicines and Healthcare products Regulatory Agency (MHRA)  
   www.mhra.gov.uk

2. The British National Formulary (BNF)  
   www.bnf.org

3. The Electronic Medicines Compendium (eMC)  
   www.emc.medicines.org.uk

4. Scottish Medicines Consortium (SMC)  
   www.scottishmedicines.org.uk

5. NHS Health Scotland & ASH Scotland (2007). Smoking Cessation Update 2007:  
   Supplement to the 2004 Smoking Cessation Guidelines for Scotland. NHS Health  
   Scotland

   Scotland, Helping smokers to Stop”. NHS Health Scotland
Appendix 1
Useful Contacts/Information

Local: -
Smoking Matters Service 0845 602 6861
www.smokingmatters.nhs.net
Email dg.smokingmatters@nhs.net

Or write to: -
Smoking Matters Service
Gardenhill Primary Care Centre
Castle Douglas
DG7 3EE

National: -
Websites
www.canstopsmoking.com
www.ashscotland.org.uk
www.healthscotland.com

Smokeline Scotland 0800 84 84 84
## Appendix 2
### Pregnant Women: NRT Risk/Benefit Assessment

Name of client ____________________________

<table>
<thead>
<tr>
<th>Topic of Discussion</th>
<th>Risks to Mother</th>
<th>Risks to Foetus</th>
<th>Tick when Discussed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dangers of continued smoking</td>
<td>Over 4000 chemicals</td>
<td>Over 4000 chemicals</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vasoconstriction</td>
<td>Vasoconstriction</td>
<td></td>
</tr>
<tr>
<td></td>
<td>High Carbon Monoxide levels</td>
<td>High Carbon Monoxide levels</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reduced Oxygen levels</td>
<td>Reduced Oxygen levels</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nicotine</td>
<td>Nicotine</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Smoking related diseases</td>
<td>Developmental problems</td>
<td></td>
</tr>
<tr>
<td>Risks of Nicotine through smoking</td>
<td>High risk</td>
<td>High risk</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vasoconstriction</td>
<td>Vasoconstriction</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pre-eclampsia</td>
<td>Premature birth weight</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Miscarriage</td>
<td>Underweight</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risks of cleaner nicotine in NRT products</td>
<td>Lower risk</td>
<td>Lower risk</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vasoconstriction</td>
<td>Vasoconstriction</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pre-eclampsia</td>
<td>Premature birth weight</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Miscarriage</td>
<td>Underweight</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benefits of NRT</td>
<td>Normal Carbon Monoxide levels</td>
<td>Normal Carbon Monoxide levels</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Increased oxygen levels</td>
<td>Increased oxygen levels</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clean nicotine</td>
<td>Clean nicotine</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reduce withdrawal symptoms</td>
<td>Reduce withdrawal symptoms</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Stops smoking</td>
<td>Healthier outcome</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Healthier outcome</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please sign below to confirm that:

1. The person recommending NRT has explained to me the use of nicotine replacement therapy (NRT) in Pregnancy
2. I have understood the information that has been given to me
3. I have tried but am unable to stop smoking without the help of NRT
4. I have been advised how to use NRT
5. I have been advised not to exceed the recommendation dose
6. I understand I must refrain from smoking while using NRT

Signatures:

Client

..............................................................

Health Care Professional ..............................................................

Designation/Location..............................................................

Date ..............................................