CALDERDALE PRIMARY CARE TRUST

PATIENT GROUP DIRECTION FOR THE SUPPLY AND ADMINISTRATION OF MEDICINES BY NON-MEDICAL PERSONNEL

Supply of Varenicline for Smoking Cessation by Community Pharmacists

APPROVED FOR USE BY:

Prescribing Lead, Calderdale Clinical Commissioning Group  Dr N Taylor
Head of Quality Penny Woodhead
Senior Pharmacist (Patient Safety) Helen Foster

OBJECTIVES OF CARE/RATIONALE

a) To provide ease of access to Varenicline (Champix®▼) supply through community pharmacies

b) To enable a one stop service for clients attending the Pharmacy-based stop smoking service who wish to use Varenicline

c) To make best use of available professional skills

d) To make best use of resources

Date of PGD: 10th May 2012
Valid Until: 10th May 2014
Review Date: 10th February 2014 – PGD expiry extended until 10th May 2015 by Ian Hughes (Head of Democratic and Partnership Services) on behalf of CMBC on 8th May 2015.
CALDERDALE PRIMARY CARE TRUST

Patient Group Direction

<table>
<thead>
<tr>
<th>Definition of patient condition this is intended to address</th>
<th>For adults who are accessing Pharmacy Stop Smoking Services and are assessed as suitable for varenicline treatment as an aid to stop smoking.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relevant National Guidelines and Information Sources</td>
<td>British National Formulary 63 (March 2012) London: BMA &amp;RPSGB</td>
</tr>
</tbody>
</table>
|                                                            | Manufacturers’ Summary of Product Characteristics (SPC) for Champix®: [www.medicines.org.uk](http://www.medicines.org.uk)  
http://www.medicines.org.uk/EMC/medicine/19045/SPC/CHAMPIX++0.5+mg+film-coated+tablets%3b+CHAMPIX++1+mg+film-coated+tablets/  
(Accessed online 01/05/12)  

NICE TA123 ‘Varenicline for smoking cessation’  
http://www.nice.org.uk/TA123 July 2007 (Accessed online 01/05/12)  

Committee on Safety of Medicines advice Varenicline: adverse psychiatric reactions, including depression  
http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON087901 (Accessed online 01/05/12)  

NICE: Public health guidance, PH10 - Issued: February 2008  
Smoking cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach communities.  
[http://guidance.nice.org.uk/PH10](http://guidance.nice.org.uk/PH10) (Accessed online 01/05/12) |
| CLINICAL CONDITION OF PATIENT GROUP                          |                                                                                                                                                                                                  |
| Description of patients included in treatment               | • Dependent smoker (i.e. they smoke within 30 minutes of waking up and/or find quitting unaided difficult) identified as sufficiently motivated to quit (willing to set a quit date between days 8 and 14 of starting treatment) and be willing to continue a course of treatment which includes behavioral support for 12 weeks (weekly intervals for the at least the first 4 weeks) unless unable to because of side effects  
• Clients aged 18 years or over  
• Consent has been obtained and recorded* |

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- A relevant medical history is taken and documented.
- There are no contraindications or cautions for treatment with Varenicline.
- Completion of client assessment form (see appendix 2) in conjunction with the client assessment form guidance (appendix 1.).

*Clients must be informed that information relating to the supply of Varenicline under PGD needs to be passed to other health service organisations, in particular their GP and their local NHS Stop Smoking Services to ensure proper record keeping and patient safety.*

**The client’s written consent must be obtained before information can be passed.**

<table>
<thead>
<tr>
<th>Description of patients excluded from treatment under the terms of this PGD</th>
<th>Pharmacists have 3 options for Clients who are excluded:</th>
</tr>
</thead>
</table>
| - Tobacco users who are not sufficiently motivated to quit or use Varenicline.  
- Client under the age of 18 years  
- Clients who have a history of depression or other psychiatric disorders (including eating disorders) (as this group may be at increased the risk of impulsive self-harm or suicide)  
- Pregnancy  
- Breastfeeding  
- Hypersensitive to Varenicline or any of the excipients  
- Renal impairment, CKD Stage 4 (eGFR less than 30ml/min/1.73m²) *(If unsure of renal function in elderly Client refer to a GP). See BNF ‘Prescribing in renal impairment’ for further information.*  
- Clients with Epilepsy should be referred to their GP *(Varenicline has not been investigated with this group of Clients so they need to be advised of this and require special monitoring)*  
- No valid consent for either treatment or for information being passed to their GP and Stop Smoking Services. For Clients over 18 with mental capacity issues see Mental Capacity Act consent pathway.  
- Clients currently prescribed or using NRT or Bupropion. | a) Consider using Nicotine Replacement as an alternative treatment option  
 b) Refer clients to their GP when the client excluded by the terms of this PGD but the SPC does allow for |
varenicline to be prescribed

c) Refer clients to their GP when the client is deemed not eligible for varenicline, but client wishes to try an alternative to NRT

Document action taken in the Clients Stop Smoking advisor notes

Patients self exclusion – action

If applicable consider NRT or offer a referral to their GP or Specialist Stop Smoking Service for further assessment and advice

Document action taken in the Clients Stop Smoking advisor notes

<table>
<thead>
<tr>
<th>TREATMENT</th>
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**Names of drugs/dose**  
Champix®▼ (Varenicline) 0.5mg film coated tablets  
Champix®▼ (Varenicline) 1mg film coated tablets

**Legal status of drugs**  
P = pharmacy  
POM = Prescription only medicine  
GSL = General sales list  
POM - Prescription only medicine.

**Frequency of drugs**  
The standard treatment course is 12 weeks.  
Dosage is outlined as in **Total dosage and number of times** section below  
1st supply – 2 weeks (titration pack)  
2nd supply – 4 weeks  
3rd supply – 4 weeks  
4th supply – 2 weeks (to complete the course)  

**Length of course**  
Varenicline is licensed for up to 24 weeks. Most Clients who stop smoking and remain abstinent will stay on varenicline for 12 weeks only.

Clients who report experiencing a strong urge to restart smoking can, following suitable review, be offered to use the starter pack in reverse for the final 2 weeks of the 12 week course, as a method of tapering. This allows the Client to assess whether urges to smoke are returning and if so, to request a longer course.

Option for 4th supply- titration pack
On the rare occasions where clients request a longer course, the client may be supplied with an additional course of up to 12 weeks treatment at 1mg twice daily.

5th supply – 4 weeks  
6th supply – 4 weeks  
7th supply – 4 weeks

In smokers who did not become fully abstinent at quit day but established abstinence thereafter, a longer course may also be considered which can be supplied for up to additional 12 weeks.

5th supply – 4 weeks  
6th supply – 4 weeks  
7th supply – 4 weeks

When additional treatment courses are supplied the service commissioner must be informed in every instance. This is to allow monitoring of the frequency of additional supply.

Any rationale for additional treatment beyond the 12 weeks / tapering doses should be documented in the clients Stop Smoking advisor notes.

<table>
<thead>
<tr>
<th>Method and route of administration</th>
<th>Oral administration.</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Swallow tablets whole with water. Take with or without food.</td>
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</table>

| Total dosage and number of times | **Clients should be treated for 12 weeks.** There should be clear labelling to indicate instructions to follow for the course.  
Smokers set a date to stop smoking and treatment with Varenicline should start 1 to 2 weeks before this date.  

**Days 1 – 3:**  
0.5 mg (white tablets) once daily  

**Days 4 – 7:**  
0.5 mg twice daily  

**Day 8 to the end of treatment:**  
1 mg (light blue tablets) twice daily  
For clients who cannot tolerate Varenicline because of adverse effects eg nausea the dose can be temporarily or permanently lowered to 0.5mg twice daily as per SPC  

The rationale for dose reduction should be documented in the clients Stop Smoking advisor notes. |
| **Follow up treatment** | Clients will be seen by the Stop Smoking Advisor weekly for at least 4 weeks after the quit date and by the pharmacist at each supply of Varenicline.  
Criteria for the pharmacist stopping Varenicline treatment immediately:  
- The Client does not want to continue treatment.  
- The stop smoking advisor or pharmacist believes that Varenicline treatment is no longer appropriate.  
- An absolute contra-indication is brought to light or develops.  
- A Client develops agitation, depressed mood, suicidal thoughts or other serious mood changes (client to be referred to GP for prompt medical advice)  
- Side effect is so severe as to impair quit attempt |
| **Advice for patients before treatment** | Issue manufacturer’s Patient Information Leaflet (PIL).  
http://emc.medicines.org.uk/medicine/10467/PIL  
Advice to clients should include specific product advice plus the following general advice on:  
- Quit date 7 to 14 days after initiation  
- Instruct on correct use and daily dose of Varenicline.  
- Mode of action of Varenicline and that Varenicline does not remove all temptation to smoke, but it does make abstinence easier  
- Possible side effects and actions clients can take to manage them  
- Effects on driving, using machinery or other cognitive tasks. Clients should exercise caution before driving or using machinery until they are reasonably certain that Varenicline does not adversely affect their performance  
- Inform client of the possible link between Varenicline and depression/suicide ideation and that they must stop treatment immediately and seek prompt medical advice if they suffer from agitation, depressed mood or suicidal thoughts.  
- Possibility of withdrawal symptoms (with an increase in irritability, urge to smoke, depression, and/or insomnia in up to 3% of patients).  
- Possible changes in the body on stopping smoking, e.g. weight gain and how to manage this. |
- 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.

- Clients taking Theophylline should be informed to contact their GP for advice regarding monitoring of their Theophylline levels. This is an effect due to smoking cessation and is not as such an interaction with Varenicline.

- Clients taking Warfarin should contact their Anticoagulation clinic to arrange an earlier INR test. This is an effect due to smoking cessation and is not as such an interaction with Varenicline.

- Clients taking insulin should be informed to consider increasing their blood glucose monitoring. This is an effect due to smoking cessation and is not as such an interaction with Varenicline.

- How and when to obtain next supply of Varenicline from the pharmacy

**Further support and advice**
Clients wanting more information can contact:
- Calderdale Stop Smoking service on 01422 281505 or email help.2quit@swyt.nhs.uk
- The NHS Smoking Helpline 0800 1690169
- The NHS Pregnancy Smoking Helpline 0800 1699169
- NHS Direct 0845 46 47

**Potential reactions**
Refer to the SPC for a full list of possible side effects.

- Very Common - Abnormal dreams, insomnia, Headache, nausea
- Common - Increased appetite, Somnolence, dizziness, dysgeusia, Vomiting, constipation, diarrhoea, abdominal distension, stomach discomfort, dyspepsia, flatulence, dry mouth, Fatigue

The MHRA have warned that there is a possible link between varenicline and psychiatric adverse events, particularly agitation, depression, and suicidal ideation.

Smoking cessation is often associated with nicotine withdrawal symptoms (agitation, insomnia, tremor, sweating) some of which are also recognized side effects of Varenicline.

**Managing and reporting**
Clients can self-report adverse reactions to the MHRA.
### adverse incidents

Using the electronic form at [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk) or by telephone on 0808 100 3352.

**All** adverse events should be reported by the pharmacist working under the PGD through the Yellow Card Scheme: [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk). Champix® is currently being monitored intensively by the CHM and MHRA and remains a ▼ drug.

Clients who report agitation/ depression /suicide ideation/ change of mood must stop treatment immediately and seek prompt medical advice.

Clients who report new or worsening cardiovascular symptoms a must stop treatment immediately and seek prompt medical advice.

### Concurrent medication

Consult BNF/SPC for full and updated details. For further advice contact the Newcastle Regional Drug and Therapeutics Centre

From trial data, Varenicline has no clinically meaningful drug interactions. No dosage adjustment of Varenicline or co-administered medicinal products is recommended. Please consult the SPC and BNF for full list of recommendations.

Physiological changes resulting from smoking cessation, with or without treatment with Varenicline, may alter the pharmacokinetics or pharmacodynamics of some medicinal products, for which dosage adjustment may be necessary (examples include theophylline, warfarin and insulin). As smoking induces CYP1A2, smoking cessation may result in an increase of plasma levels of CYP1A2 substrates. Clients on warfarin, theophylline and insulin may need closer monitoring. This is covered in the **Advice for patients before treatment** section.

### Supporting facilities required

**Surgery, clinic or domiciliary events**

The Level 2 NHS Stop Smoking Service must be carried out within the pharmacy consultation room (as defined by for the MUR service).

### STAFF

**Professional qualifications required**

Pharmacist (registered with GPhC)
<table>
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<tr>
<th>Any exceptions to above</th>
<th>None</th>
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</thead>
</table>
| Extra training and qualifications | Pharmacist either trained themselves or working with a pharmacy-based Stop Smoking Advisor accredited to provide Level 2 Stop Smoking advice working in a Calderdale pharmacy authorised by the PCT to provide the Stop Smoking enhanced service. The pharmacist must have received training in use of this patient group direction provided by NHS Calderdale. This training will include:  
- appropriate training to carry out clinical assessment of the client leading to a decision that requires treatment according to the indications listed in this PGD  
- working under PGDs for the supply and administration of medicines  
Has undertaken training appropriate to this PGD |
| Experience or competence required | As per extra training and qualifications above |
| Continuing education required | The pharmacist must be aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual to keep up to date with continued professional development. |

**MANAGEMENT AND MONITORING**

**Authors of PGD**

- **Lead Author Ruth Buchan** Senior Pharmacist (Community Pharmacy)
- **Dr Nigel Taylor** GP
- **Sarah Beeden** Practice Nurse
- **David Green** Immunisation Co-ordinator
- **Helen Foster** Senior Pharmacist (Patient Safety)
- **Robbie Turner** Chief Executive Officer Community Pharmacy West Yorkshire

**Records to be kept for audit purposes**

- Client Assessment Form for Varenicline (appendix 2)
- Notes in Stop Smoking Advisor notes as outlined within the PGD and Service Specification

**Date of writing**

8th May 2012

**Record of names of those authorised to work under this Patient Group Direction is held**

- Ruth Buchan  
  Senior Pharmacist (Community Pharmacy)  
  NHS Calderdale
AUTHORISATION OF NAMED HEALTH PROFESSIONAL TO SUPPLY OR ADMINISTER MEDICINES UNDER PATIENT GROUP DIRECTIONS

**Supply of Varenicline for smoking cessation by community pharmacists**

I have read and understood the Patient Group Direction and agree to work within its confines.

<table>
<thead>
<tr>
<th>Named Health Professional</th>
<th>Designation</th>
<th>Signature of Health Professional</th>
<th>Date of Varenicline PGD training</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
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Appendix 1. – Client Assessment Form Guidance for Stop Smoking Advisors
How to complete and why?

Client Assessment Form Guidance for Stop Smoking Advisors - How to complete and why?
For clients who have a preference for Varenicline (Champix®) for their smoking cessation therapy, the following form (“Client assessment form Varenicline”) should be completed. There are separate sections to assess past mental health, current mental health and medication history.

It is also important to consider a person’s social history. Often a person will not think that they are depressed or low in mood but may be exerting social signs that they are. For example: if a client is heavy or binge drinking then this may indicate signs of depression and would warrant referral to the client’s GP for further assessment or use of NRT in these clients.

Social history
In the client assessment form (social history section) if the client drinks:
☐ > 28 units per week (men)
☐ > 21 units per week (women)

the client should be offered referral to the Calderdale Substance Misuse Service (alcohol) on telephone: 0800 328 6397 or 01422 361111. The pharmacist should make an assessment if the client is eligible for treatment with varenicline under these circumstances.

Past medical history
Clients who have a history or depression or other psychiatric disorders (including eating disorders) may be at increased the risk of impulsive self-harm or suicide. These clients cannot be issued medication.

If the client answers yes to either of these questions they must be referred to their GP for further assessment or they can be prescribed NRT immediately, via the voucher scheme. The client can decide what they wish to do. Please stress that the GP may still not be able to prescribe the tablets due to other medical conditions/medication.

Conditions where the client will not be appropriate for these treatments are detailed in the PGDs for varenicline.
Client Assessment Form for Varenicline

As you have chosen to consider Varenicline as your medication to help stop smoking, please complete the questions below. As it has already been discussed with you, treatment with Varenicline may have side effects. This medicine may not be appropriate for you if you have certain medical conditions. If you do not want to answer a question or want to speak to a smoking advisor/pharmacist confidentially, please highlight this to the advisor.

If you are commenced on Varenicline a letter will be sent to your GP to inform them. They will be asked to contact us if they have any concerns with you receiving the treatment.

Social history

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>In a week how many units would you drink?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 unit = half a pint, 1 unit = 125ml (small glass) of wine, 1 unit = single measure of a spirit</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Past medical history

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you have a history of feeling depressed, low in mood?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you ever been diagnosed with bipolar disorder?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you ever been prescribed medication for low mood, depressions or anxiety? e.g antidepressants</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you ever been diagnosed with a seizure (fits) disorder?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you ever been diagnosed with an eating disorder?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Current medical history

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>During the last month, have you often been bothered by feeling down, depressed or hopeless?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>During the last month, have you often been bothered by having little interest or pleasure in doing things?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you have reduced kidney function? (also called renal impairment)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Medication history

Please provide a list of your current medications to the advisor for information (this will be documented in your management plan). Please include medicines that you buy from a pharmacy plus any herbal products or vitamins you are taking.

Patient name (please print): ........................................

Signature: ............................................... Date: .....................

I confirm that the information provided above is a true reflection and allows the Community Pharmacist to provide the most appropriate, most safe, advice and treatment for me.