With all of us in mind

South West Yorkshire Partnership NHS
NHS Foundation Trust

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Smoking Cessation Guidelines

Provision of Stop Smoking Medications

Commencing 30.8.14

Review date 30.4.16

South West Yorkshire Partnership NHS Foundation Trust

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Yorkshire Smokefree

Smoking Cessation Drug Therapy

General Prescribing Issues

The vast majority of trials of smoking cessation drugs include motivated subjects only and intense behavioural support is available. It is unclear whether similar quit rates will be achieved in practice where these levels of counselling are unlikely. In order to achieve the best quit rates **smokers should receive counselling from the smoking cessation service, or by a smoking cessation advisor working under the locally enhanced service (LES), wherever possible.** This is particularly important for bupropion and varenicline where there is no evidence for effectiveness without behavioural support.

Therapy to aid smoking cessation should be chosen according to the smoker's likely compliance, availability of counselling and support, previous experience of smoking cessation aids, contra-indications, adverse effects, patient co-morbidities and the smoker's preferences.

Smoking cessation therapies should not be added to repeat prescription.

Nicotine Replacement Therapy (NRT)

Should not be used if:

1. It is contra-indicated: Patient is under 12 years old; known hypersensitivity to active ingredient or any component of the NRT product.
2. NRT, used properly, has been ineffective during a previous quit attempt.
3. NRT has not been tolerated.

All patients should be advised, wherever possible, to attend the smoking cessation service (or see a smoking cessation advisor working under the LES) in preference to simply issuing a prescription. Intensity of counselling is strongly linked to quit rates and one very large study in the USA found that, with intensive protracted behavioural support, together with aggressive use of NRT, about one in four smokers stopped for at least a year who would not otherwise have done so.

Smokers attending the smoking cessation service may receive NRT via the voucher scheme thus ensuring ongoing behavioural support and reducing GP appointments.

If a patient has made a successful quit attempt using NRT, but then relapsed, this is not an indication to try a different drug.

Combining two forms of NRT may be considered for patients who were previously unsuccessful with a single form of NRT.

Initial supply of NRT should be for **one week** only; a second supply should be issued only if the patient demonstrates a continuing attempt to stop smoking. Further supplies should be given weekly for the next three weeks and then fortnightly until the course is completed. NRT should be used with caution in patients who have: severe or unstable CVD; recent MI or CVA; uncontrolled hyperthyroidism; diabetes mellitus; hepatic impairment; renal impairment; pregnancy, breast-feeding (intermittent therapy such as gum, inhalator, preferable). Oral preparations should be used with caution in patients with: oesophagitis, gastritis, peptic ulcer. Patches should be used with caution in patients who have skin disorders (should not be placed on broken skin).

It is recognised that any risks that may be associated with NRT are substantially outweighed by the well established dangers of continued smoking.

VARENICLINE AND BUPROPION

Other therapies (bupropion and varenicline) have more side-effects, interactions and contra-indications than NRT. Varenicline is a 'black triangle' drug and any adverse reactions should be reported via the yellow card system. changes in behaviour or thinking, anxiety, psychosis, mood swings, aggressive behaviour, depression, suicidal ideation and behaviour and suicide attempts have been reported in patients attempting to quit smoking with varenicline in the post-marketing experience. Not all patients had stopped smoking at the time of onset of symptoms and not all patients had known pre-existing psychiatric illness. Clinicians should be aware of the possible emergence of significant depressive symptomatology in patients undergoing a smoking cessation attempt, and should advise patients accordingly. varenicline should be discontinued immediately if agitation, depressed mood or changes in behaviour or thinking that are of concern for the doctor, the patient, family or caregivers are observed, or if the patient develops suicidal ideation or suicidal behaviour. In many post-marketing cases, resolution of symptoms after discontinuation of varenicline was reported although in some cases the symptoms persisted; therefore, ongoing follow up should be provided until symptoms resolve.

Buproprion is a centrally-acting noradrenaline/dopamine reuptake inhibitor. Neuropsychiatric reactions have been reported . In particular, psychotic and manic symptomatology has been reported mainly in patients with a known history of psychiatric illness.

Depressed mood, rarely including suicidal ideation and suicide attempt, may be a symptom of nicotine withdrawal. In addition, smoking cessation, with or without pharmacotherapy, has been associated with exacerbation of underlying psychiatric illness (e.g. depression).

Bupropion (Zyban) via a GP Prescription

Wherever possible, any client who requests bupropion should be referred to a smoking cessation advisor before a prescription is issued. This will help to ensure that the smoker is committed to quitting and that they receive appropriate counselling and support.

If the patient is attending the stop smoking service they should present to the surgery with a letter **every time they require a prescription** (appendix 4 and 5). This confirms that they are still receiving appropriate behavioural support and are still committed to stopping smoking.

Initial supply of bupropion should only be for **3 weeks** (the client should set a quit date sometime during the 2nd week of treatment); this will give time to attend the smoking cessation service before requiring a further prescription. A second prescription should only be issued if the patient demonstrates a continuing attempt to stop smoking. Letter requesting further supply of bupropion to be issued by the stop smoking service (Appendix 5)

Except in exceptional circumstances patients should receive **a two week supply** of bupropion on each ongoing prescription. Patients should be attending a smoking cessation advisor for **weekly** behavioural support and monitoring. Limiting the quantity of medication prescribed helps to ensure ongoing support and reduces waste should the quit attempt be unsuccessful.

Blood pressure should be measured before, and monitored regularly during, treatment.

Varenicline (▼Champix) via a PGD and participating Pharmacist

From the 1st March 2015 a PGD is in operation for the supply of Varenicline through a Pharmacy scheme. (Appendix 1)

The PGD allows certified pharmacists to supply Varenicline to eligible clients under specified circumstances without the requirement for a GP intervention or prescription. This means that GPs will no longer be routinely prescribing Varenicline as part of the Stop Smoking Service programme.

Under NICE Guidance, GPs should refer clients to the service for support before prescribing any medication. This will continue as normal, whereby the stop smoking adviser works with the client to determine appropriate medication once the GP has referred the client for stop smoking support.

Advisers and Pharmacists must adhere to the client exclusion and inclusion eligibility criteria set out in the PGD (see below): these are the criteria that pharmacists will use to determine eligibility:

Exclusion Criteria for Varenicline. The following groups will not be eligible to receive varenicline under the PGD:
• Person is aged under 18 years • Pregnant or breastfeeding women • Persons with renal disease • Pregnant or breastfeeding women • Persons with known sensitivity to Varenicline or any of its excipients • Persons with a history of psychiatric illness

There may be exceptions where a person is not eligible for use of Varenicline under the PGD but may be considered eligible by a GP or qualified prescriber under strictly supervised circumstances. In these exceptional cases, GPs or prescribers may still issue a prescription to a client for Varenicline, but this is expected to be a small number of cases.

GP practices will be informed if their patient is receiving Varenicline, in the form of a triplicate copy of the completed Varenicline voucher sent from the pharmacist who is responsible for that patient under the PGD. (Appendix 7)

Guidance for Stop Smoking Advisors can be found in Appendix 6

Supply of Varenicline Via a GP prescription

Wherever possible, any client who requests varenicline should be referred to a smoking cessation advisor before a prescription is issued. This will help to ensure that the smoker is committed to quitting and that they receive appropriate counselling and support.

If the patient is attending the stop smoking service and has not been deemed suitable to receive varenicline via the PGD then they should present to the surgery with a letter **every time they require a prescription** (appendix 4 and 5). This confirms that they are still receiving appropriate behavioural support and are still committed to stopping smoking.

Initial supply of varenicline should be for a 2 week 'starter pack' **plus** two further week's supply (usually 28 x 1mg tablets); the client should set a quit date sometime during the 2nd week of treatment - this will give time to attend the smoking cessation service before requiring another prescription. Further prescriptions should only be issued if the patient demonstrates a continuing attempt to stop smoking.

Except in exceptional circumstances patients should receive **a two week supply** of varenicline on each ongoing prescription. Patients should be attending a smoking cessation advisor for weekly behavioural support and monitoring. Limiting the quantity of medication prescribed helps to ensure ongoing support and reduces waste should the quit attempt be unsuccessful.

- Abrupt withdrawal of varenicline can lead to irritability, **depression** and insomnia, as well as increasing the risk of relapse. **Prescribers should consider dose-tapering at the end of a treatment course, especially if there is any history of depression.**

- Varenicline should not be prescribed for longer than 12 weeks. A trial of varenicline for a further 12 week period (i.e. 24 weeks in total) showed little difference in continued abstinence at 52 weeks and is therefore considered not cost-effective.

- Varenicline (▼Champix) is a 'black triangle' drug. Prescribers should report all suspected adverse reactions via the yellow card scheme.

NB: - The information contained within this document is not comprehensive. If prescribing, reference should always be made to standard reference sources such as the BNF www.bnf.org **and Summary of Product Characteristics (Datasheet)** http://www.medicines.org.uk

Rationale for Prescribing Smoking Cessation Medications

Assessing Nicotine Dependence

Assessing nicotine dependence is the process by which an advisor establishes the extent to which clients are addicted to tobacco products. The nicotine dependence of all clients must be assessed. Advisors must use at least one of the following two approaches;

- Quantitative approach
- Heaviness of smoking index

Quantitative Approach

Tailoring stop smoking support for an individual starts with assessing their dependence on nicotine, as this will have a bearing on the severity of the withdrawal symptoms they may experience, and therefore the intensity of support they require. It may also be used to indicate the most appropriate medication. The Fagerström test for nicotine dependence (FTND) provides a quantitative measure and is the most widely used. It consists of six questions. The higher a client scores, the greater their nicotine dependency.

Heaviness of Smoking Index

The two most important indicators of dependence, however, are considered to be: 'How soon after you wake do you smoke your first cigarette?' and 'How many cigarettes per day do you smoke?' It is therefore deemed adequate to use just these two questions as a shortened version of the FTND. Cigarette consumption alone is not a good indicator of dependence, as it does not take into account the different ways people smoke their cigarettes. This may be particularly true for smokers who cut down the number they smoke but continue to get the same amount of nicotine from their reduced number of cigarettes by taking deeper and more frequent puffs, smoking more of each cigarette or blocking the vent holes.

NHS Stop Smoking Service. Service and Monitoring Guidance 2010/11

Deciding Which Therapies To Use

When deciding which therapies to use and in which order, discuss the options with the client and take into account:

- Whether a first offer of referral to the NHS Stop Smoking Service has been made
- Contra-indications and the potential for adverse effects
- The client's personal preferences
- The availability of appropriate counselling or support
- The likelihood that the client will follow the course of treatment
- Their previous experience of smoking cessation aids

Consider offering a combination of nicotine patches and another form of NRT (such as gum inhalator, lozenge or nasal spray) to people who show a high level of dependence on nicotine or who have found single forms of NRT inadequate in the past.

National Institute for Health and Clinical Excellence. Public Health Guidance 10. Smoking Cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach groups. February 2008.

FAGERSTROM TOLERANCE QUESTIONNAIRE

Please circle one response per question

1. How soon after you wake do you smoke your first cigarette?

(3) within 5 minutes (2) 5 – 30 minutes

(1) 31 – 60 minutes (0) after 60 minutes

2. Do you find it difficult not to smoke in places you shouldn't, such as in shops, on the bus etc?

(1) YES (0) NO

3. Which cigarette would you most hate to give up?

(1) First thing in the morning (0) any other one

4. How many cigarettes do you smoke each day?

(0) 10 or fewer (1) 11 – 20

(2) 21 – 30 (3) 31 or more

5. Do you smoke more frequently during the first hours after waking up than during the rest of the day?

(1) YES (0) NO

6. Do you still smoke if you are so sick that you are in bed most of the day?

(1) YES (0) NO

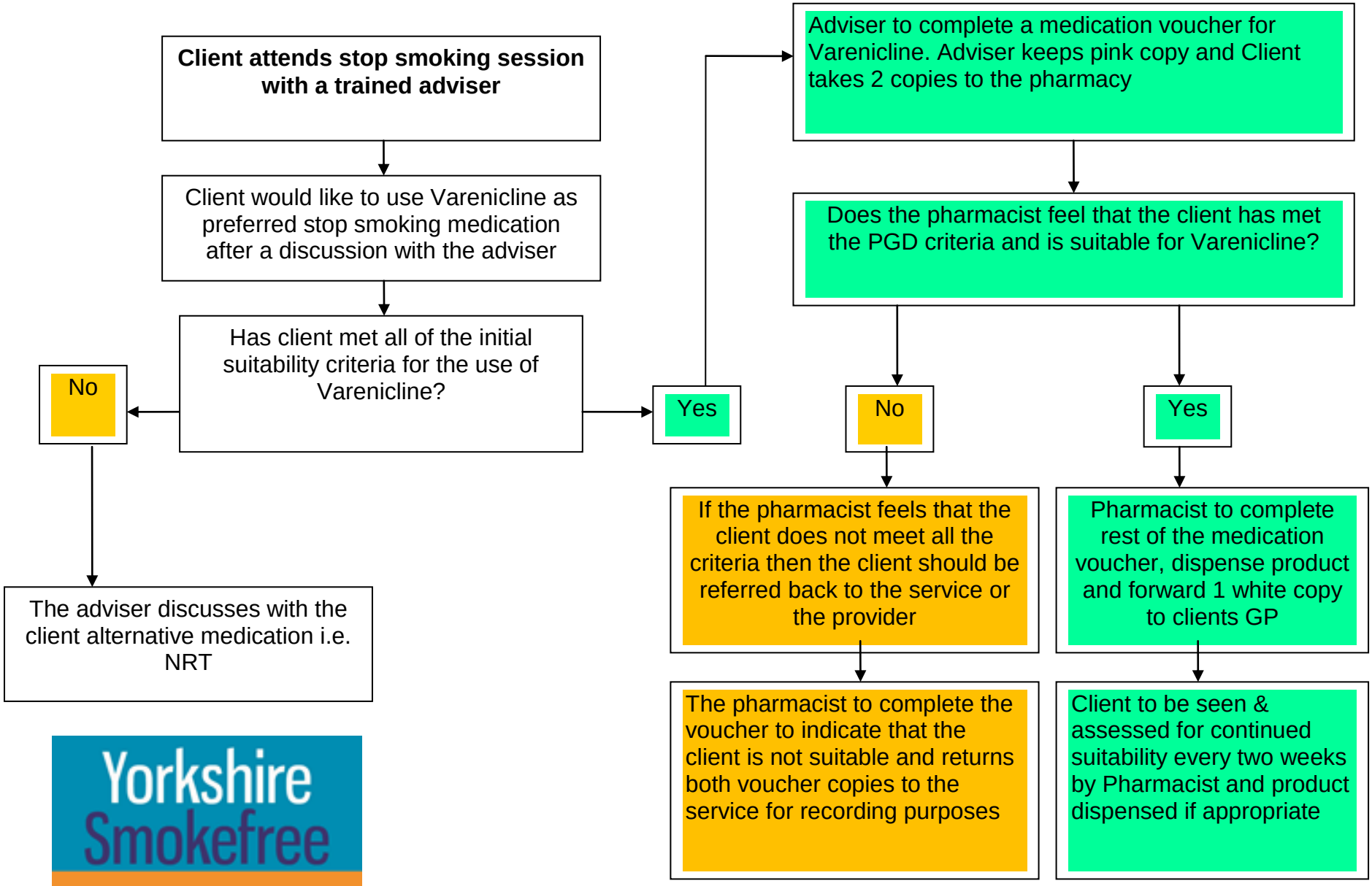
Add the total number of points to score your level of tobacco dependence

0 – 2	3 – 4	5	6 -7	8 -10
Very low	low	medium	high	very high

Heatherton TF, Kozlowski LT, Frecker RC and Fagerstrom KO (1991) 'The Fagerstrom Test for Nicotine Dependence: A revision of the Fagerstrom Tolerance Questionnaire.' British journal of Addictions 86(9):1119-27

APPENDIX ONE

PROCESS FOR ASSESSING CLIENT SUITABILITY AND THE PRESCRIBING OF VARENICLINE VIA A Patient Group Directive



Yorkshire Smokefree

APPENDIX 2

Smoking Cessation Guidelines

NICE Guidance

NICE guidance supports the prescription of NRT, Bupropion and Varenicline to smokers who wish to stop smoking provided that:

- Smokers are offered advice and support
- A quit date is agreed and the initial prescription is sufficient to last two weeks after the quit date
- Further Prescriptions/vouchers are given only to people who have been reassessed and have demonstrated that their quit attempt is continuing.

Additional Information

- Anyone who smokes within 30 minutes of waking/or smokes more than 20 cigarettes daily will usually need to start with the highest strength.
- In pregnancy and breast feeding, the benefits of NRT are likely to outweigh the risks in any patient who cannot stop smoking without it. Some products are contraindicated and liquorice flavoured products should be avoided. e.g. Nicotinell Liquorice gum and Niquitin CQ gum should be avoided.

NRT Product list and cost comparison (Recommended starting doses only)

Level of Dependency	Number of Cigarettes per day	Type of NRT	Dose and Treatment Duration	Weekly Cost
Low to Medium	<10	Transdermal Patch	Apply on waking to dry, non-hairy skin on hip, chest or upper arm. Remove after specified time	Niquitin CQ 14mg/24 hours (7) = £9.97 Nicorette Invisipatch 15mg/16hrs (7) = £9.97 Nicorette 15mg/16hrs (7) = £9.97
	<20	Transdermal Patch	Apply on waking to dry, non-hairy skin on hip, chest or upper arm. Remove after specified time	Nicotinell TTS 20 (14mg/24 hours) (7) = £9.40 Nicorette Invisipatch 15mg/16 hour (7) = £9.97
	<20	Gum 2mg	One 2mg piece of gum chewed slowly for 30 minutes on urge to smoke (Max 15 pieces daily)	Nicorette (105) = £9.27 NIcorette (210) = £14.82 Nicorette (Icy white (105) 9.76
	<20	Microtab 2mg	Oral administration (sublingual)- 2mg per hour (Max 40 tabs per day)	Nicorette (105) = £13.12
	<20	Lozenge Mini 1.5mg and 2mg	Use one lozenge (Mx.8 to 12) on urge to smoke not to exceed 15 per day	Nicorette Cools (80) = £11.48 Niquitin (60) = £8.93
Medium to High	>20	Transdermal Patch	Apply on waking to dry, non-hairy skin on hip, chest or upper arm. Remove after specified time	Nicorette 15mg/16 hour (7) = £9.97 Nicorette Invisipatch 25mg/16 hour (7) = £9.97 Nicorette Invisipatch (14) =£16.35 Niquitin CQ 21mg/24hrs (7) = £9.97 Nicotinell TTS 30 21mg/24hrs (7) =£9.97 Niquitin CQ 21mg/24hrs (14) = £18.79 Niquitin CQ 21mg/24hrs (7) = £9.97
	>20	Lozenge Mini 4mg	Use one lozenge (Mx.8 to 12) on urge to smoke no to exceed 15 per day	Nicorette Cools (80) = 11.48 Niquitin (60) = £8.93
	>20	Mouthspray	Up to 2 sprays per dose, no more than 64 sprays per day (equiv to 4 sprays per hour for 16hrs)	Nicorette (13.2ml) = £11.48 Nicorette (26.4ml) = £18.50
	>20	Gum 4mg	One 4mg piece of gum chewed slowly for 30 minutes on urge to smoke (Max 15 pieces daily)	Nicorette Icy white (105) = £11.48 Nicorette Fresh mint (210) = £18.24 Nicorette Freshmint (105) = £11.30 Nicorette Freshfruit (105) = £11.28 Nicorette Original (105) = £11.28
	>20	Microtab 2mg	Oral administration (sublingual)- 4mg per hour (Max 40 tabs per day)	Nicorette (105) = £13.12
	>20	Inhalator 15mg	To be used whether the urge to smoke is felt or to prevent cravings (max 6 cartridges per day)	Nicorette (36) = £22.33
	>30	Nasal spray	To be used to prevent cravings (Max 32mg or 64 sprays per day)	Nicorette 10ml = £13.40

APPENDIX 3 — Smoking Cessation Product Choices

(*please refer to Summary of Product Characteristics for full details*)

Varenicline (Champix) and Bupropion (Zyban) should normally be prescribed only as part of a programme of behavioural support

NRT
(unless specific contra-indications, not tolerated or ineffective)

Supporting Information

Patients who smoke within 30 minutes of waking and/or smokes more than 20 cigarettes daily will usually need to start with the highest strength NRT products

All forms of NRT can be used by patients with cardiovascular disease. NRT should be offered in any case where the alternative is the patient resuming smoking. In patients with cardiovascular disease that is not stable or controlled by treatment, the decision to prescribe should be made in consultation with the supervising physician.

Consideration of Risks and Benefits before supplying to patients with cardiovascular disease, hyperthyroidism, diabetes mellitus, severe renal impairment and peptic ulcer.

Pregnancy and Breast Feeding- benefits are likely to outweigh the risk in patients who cannot stop smoking without it. The 24hrs patch should be taken of at night during pregnancy.

Choice of NRT (see Appendix 2)

Patch	24hrs 21mg, 24hrs 14mg, 24hrs 7mg, 16hrs 25mg, 16hrs 15mg, 16hrs 10mg, 16hrs 15mg, 16hrs 10mg, 16hrs 5mg
Gum	4mg and 2mg
Mini Lozenges	4mg, 2mg and 1.5mg
Microtabs	2mg
Inhalator	15mg
Nasal spray	
Mouthspray	

Prescription/Supply Information

- 1 week supply for the first four weeks on verification of abstinence by a CO reading
- After 4 weeks abstinence further supply to the end of 10/12 week course on a fortnightly basis

Bupropion/Zyban®

Are there Contraindications?

Epilepsy	Seizures
Previous head injury	Bipolar disorder
MAO Inhibitors	Known CNS Tumour
Pregnant/breast feeding	
Alcohol or benzodiazepine withdrawal	
Seizures (current, previous)	
Eating Disorders	Hepatic cirrhosis
Age <18 years	
Allergy, hypersensitivity to Bupropion	

→ **Yes** Use Alternative

Are there Interactions?

Insulin	Hypoglycaemics
Antidepressants	Antipsychotics
Beta-Blockers	Anti-epileptic drugs
Systemic steroids	Anti-malarials
Cyclophoshamide	
Antiarrhythmics (type 1c)	
Sedating antihistamines	
Quinolones	Cimetidine
Levodopa	Theophylline
Orphenadrine	Tramadol

→ **Yes** Use Alternative

Prescription Information

Provide 2 weeks supply initially, and a review should be performed before further supply is considered

150mg daily for 6 days
150mg twice daily for rest of course

Max dose 150mg daily in patients at risk of seizures, renal impairment, liver disease

Course should not exceed 8 weeks (56 days)

DO NOT PLACE ON REPEAT PRESCRIPTION

Varenicline/Champix®

Contraindications?
Hypersensitivity to active substance
Age< 18 years
Pregnant/Breast feeding

→ **Yes** Use Alternative

* Epilepsy?
** Psychiatric illness (e.g.depression)?
*** Increased risk of MI?

Interactions?
Cimetidine: Avoid concomitant use

→ **Yes** Use NRT

Renal Impairment

Moderate: CrCl= <50ml/min but more than 30ml/min use **1mg daily**
Severe: CrCl= <30ml/min use **initiate at 0.5mg daily increase to max 1mg daily**
End Stage- Do no use

Prescription Information

Issue 2 weeks supply at a time

Day 1-3	0.5mg OD
Day 4-7	0.5mg BD
Day 8 to end of treatment	1mg BD

DO NOT PLACE ON REPEAT PRESCRIPTION

***** - patients with epilepsy should be closely monitored
** - changes in behaviour or thinking, anxiety, psychosis, mood swings, aggressive behaviour, depression, suicidal ideation and behaviour and suicide attempts have been reported in patients attempting to quit smoking with Champix. Champix should be discontinued immediately if the above are observed.
******* - risk/benefit ratio needs to be assessed

APPENDIX 4

Dr …….

Practice: ……...

CLIENT REQUEST TO DISCUSS VARENICLINE OR BUPROPRION

Client name: ……

Address ……

Date of birth ……

We confirm that the above client has been assessed by the Barnsley Stop Smoking Service and now wishes to discuss the use of the different therapies available to support their stop smoking attempt.

As part of the recommended behavioural support programme (DoH guidance 2012/13) the client will be monitored on a weekly basis by a Stop Smoking Advisor by use of a carbon monoxide monitor.

The clients carbon monoxide reading at the date of this letter is: ……..
6 and under denotes a non-smoker)

The client is aware that the decision to prescribe and the final choice of product rests entirely with the GP

Overleaf is a suggested algorithm for the support of smoking cessation. This has been approved by NHS Barnsley and the Area Prescribing Committee. (Please see revised protocol August 13).

Advisor details/Stamp   Date:

Appendix 5

Dr …….

Practice: ……...

Request for follow on prescription.

Bupropion (Zyban)/ Varenicline (Champix▼)

Client name: ……

Address ……

Date of birth …….

We can confirm that the above named client is currently attending for weekly behavioural support.

The clients CO reading is …… ppm
(6ppm and under denotes a non-smoker)

The client has completed the first course of medication and now requires the following:

☐ **Bupropion (Zyban)** Ongoing 2 weeks script (usually 28 tablets x 150mg) **Please do not place this prescription on repeat**	☐ **Varenicline (Champix▼)** Ongoing 2 weeks script (usually 28 tablets x 1mg) **Please do not place this prescription on repeat**

Advisor details/Stamp and signature

Issue date: ……

APPENDIX 6

Yorkshire Smokefree Barnsley

PATIENT GROUP DIRECTION (PGD) FOR VARENICLINE (CHAMPIX)

ADVISER INSTRUCTIONS AND USER GUIDE TO THE PGD – PLEASE KEEP FOR REFERENCE

This Guidance is for Advisers working in Stop Smoking Service Providers

A PGD for Varenicline took effect on 1ST MARCH 2015

The PGD allows pharmacists to supply Varenicline to clients under specified circumstances following a consultation with an adviser, without the need for a client to attend a GP appointment or request a prescription.
A voucher system will operate under the PGD, so that the adviser can issue a Varenicline voucher to the client who can then take it to a designated pharmacy for supply without the need of a prescription (FP10).

This is a new A4 Varenicline voucher in triplicate.

Key things for advisers to remember:

- Assess if client is eligible for Varenicline referring to the list of exclusions
- The exclusion criteria are very clear about who is not eligible for Varenicline under the PGD. However, exceptionally if you are not sure if they are eligible or not, as a last resort you can send them to a pharmacist with a voucher – but warning the client that they may not be eligible - and the pharmacist will make the final decision.
- If you are issuing a Varenicline voucher, please make sure you keep the pink copy for your records in case of any query from the pharmacist.
- If a client is not eligible for Varenicline, you can discuss NRT medication with them.
- If a client is not eligible under the PGD, do not send their GP a prescription request letter. The client needs to visit the GP themselves to discuss Varenicline with them. You can still offer them behavioural support during their quit attempt as usual and record their quit date and 4 week quit on Quit Manager as usual.

As usual advisers will still discuss with clients the different medication options available to them as well as assessing their addiction, client motivation and behavioural change support to determine their readiness to quit.
If the client would like to use Varenicline then the adviser should discuss the initial suitability of the product with the client.

Who is excluded from using Varenicline under the PGD?

Under the PGD, the following groups are **excluded** and may not be supplied with Varenicline under the PGD:

- Client is under 18 years
- Client is pregnant or breastfeeding
- Client has renal (kidney) disease
- Client is known to have sensitivity to Varenicline or any of its excipients
- Clients with epilepsy
- Client has a history of psychiatric illness

Clients that fall within these above groups should **not** be given a Varenicline voucher – the pharmacist would not be able to supply Varenicline under these circumstances and advisers can offer the client an alternative NRT product instead.

Advisers: please do not send a client who is clearly not eligible under the PGD to a pharmacist– its unfair to the client and it puts the pharmacist in an unfair position because they cannot supply Varenicline to the client if they fall into an excluded group – pharmacists do not have any flexibility on this.

What happens next if a client is not eligible for Varenicline?
The adviser needs to make clear to the client that they are not eligible under the PGD and they can discuss alternative NRT medication options with the client.
If the client that is excluded under the PGD is really keen to use Varenicline, then exceptionally their own GP may determine if they can be given Varenicline under strictly supervised circumstances.
An adviser can suggest the client visits their GP to discuss the possibility of using Varenicline, but advisers should **not** send a prescription request letter to the GP. Prescription request letters are longer issued under the PGD.

If the GP feels that this client can use Varenicline, the GP will issue a prescription direct to that client and provide the clinical supervision (and further prescriptions) to that client over the 12 week programme.

Advisers should still sign up and support a client who is receiving Varenicline via their GP (as you used to do anyway prior to the PGD), so just sign the client up as normal, set a quit date with them and follow them up for at least 4 weeks as usual. However the adviser cannot issue any Varenicline vouchers to that client, they must receive it via prescription from their GP.

If an adviser feels that the client is eligible for Varenicline under the PGD, then the adviser will complete the top adviser section of the Varenicline voucher. These new A4 vouchers are in triplicate with 2 white copies and one pink copy. The adviser will keep the pink copy of the completed voucher for their own records and give the client the top 2 white copies which they take to a **specified** pharmacy that is participating in the PGD scheme.

The list of participating pharmacies has been circulated and is updated periodically as more pharmacies sign up to the PGD. Clients will need to choose which specific participating pharmacy they go to and stay with that pharmacy when bringing any subsequent vouchers.

The client will be offered a consultation with the pharmacist who will assess again the suitability of Varenicline for that client by asking the client questions relating to their medical history and other medications that are currently being prescribed. Only a pharmacist can make this final decision about suitability and supply the medication – stop smoking advisers and pharmacy counter staff cannot make that final decision.

If pharmacist determines that the client is eligible to use Varenicline:

If the pharmacist is happy for the client to use Varenicline the pharmacist will then complete the pharmacist sections of the voucher and sign it. The client will sign the voucher to accept treatment and confirm the discussion that has taken place with the pharmacist. Varenicline will then be given to the client. The pharmacist keeps one white copy of the completed voucher for their pharmacy records and sends the other white copy to the client's GP.

The client must return to the same pharmacy each time, usually every 2 weeks, with their Varenicline vouchers over the 12 week course of treatment.

Clients that are using Varenicline will be seen by the Stop Smoking Advisor bi-weekly (every 2 weeks) for at least 12 weeks and by the pharmacist bi-weekly at each supply of Varenicline. The treatment programme for Varenicline is 12 weeks.

Please note the pharmacist is just ensuring the client's suitability for Varenicline, they are **not** offering the client any behavioural support for the quit attempt itself.

That is your job as an adviser - the adviser needs to continue supporting the client around their quit attempt.

If pharmacist determines that the client is <u>not</u> eligible to use Varenicline:

If the pharmacist feels that the client does not meet all of the inclusion criteria for Varenicline then the client will be referred back to the adviser to discuss alternative treatments.

The pharmacist will then return the 2 copies of the voucher back to the central Service for recording purposes.

The pharmacist at any time can request that the clients stop using Varenicline using the following criteria:

- 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

APPENDIX 7

Client Assessment Form - Varenicline (Champix) Voucher

South West Yorkshire Partnership NHS
NHS Foundation Trust

Yorkshire Smokefree Barnsley

All replies are private & confidential

Serial no: 01001

For Advisor To Complete - Client Details	
Name:	Date of Birth:
Address:	
GP Name:	
GP Practice Address:	

Advisor Details	
Advisor Name:	Advisor Signature:
Contact Telephone Number:	Location Client Seen:
Date Voucher Issued:	

For Advisor To Complete			**For Pharmacist To Complete**	
Product	**Quantity**	**Supply No.**	**Date of Supply**	**Pharmacists Initials**
Varenicline Two weeks Titration pack *(Supply No. 1 only)*	1			
Varenicline 1mg x 28 tablets *(Supply No. 2-6 only)*	1			
Varenicline 0.5mg x 28 tablets *(Supply No. 2-6 only)*	1			

For Pharmacist To Complete *Please mark with a ✔ in one box next to each statement*	**Y**	**N**
1. Aged 18 or above		
2. Tobacco dependant & sufficiently motivated to stop smoking		
3. Agreed to behavioural support during course of Varenicline		
Is the client currently:		
4. Pregnant or breastfeeding?		
Does the client have a history of:		
5. Renal disease?		
6. Epilepsy?		
7. Sensitivity to Varenicline or any of its excipients?		
8. Psychiatric illness?		

All clients must answer **YES** to **Questions 1-3** to be eligible.
If clients answer **YES** to any of **Questions 4-8**, not eligible for Varenicline via the PGD.

For Client To Complete - Consent *(in the presence of a pharmacist)*

I, _____ *(name)* confirm that the above information has been discussed with me and is an accurate record of that discussion.

I give consent to the above information being passed to my GP, pharmacist and local smoke free service.

Signature: _____ Date: _____

Voucher only available to clients registered with a Barnsley GP and are valid for 28 days from the date of issue.

For Pharmacist To Complete

I, _____ *(print name)*

confirm that the Varenicline preparation recommended and dispensed on this voucher is clinically appropriate for the client.

Pharmacist Signature: _____

Date: _____

Distribution: **Blue copy = Keep in pharmacy** Yellow copy = GP Pink copy = Retained by Smoking Advisor