

Varenicline Client Record

This document forms the comprehensive record of the client's assessment and supply of Varenicline.

Copies of completed letters and DH monitoring form must be stapled to this record. This ensures that the pharmacist retains a comprehensive record for each client as required by the PGD.

Client details	
Full Name	
Address	
Postcode	
Date of Birth	
Client ID number	Insert patient's PMR number
GP Name	
Date client enrolled for PGD	
Pharmacy name	
ODS code	F
Pharmacist responsible for supply under PGD	
GPhC registration number	

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Summary page & CLAIM FORM

To be copied at end of supply and sent to claim payment

Pharmacy _____ OSC code **F** _____

Client reference number: _____ (Patient's PMR number)

COMPLETE SHADED AREAS

Supply number	Details of supply	Date	Dose <small>Delete as appropriate</small>	Number of tablets supplied	Prescription fee due <small>Delete as appropriate</small>	Medication cost (drug tariff price)
1 <small>Initial Consultation</small>	Titration pack- 2w		Titration pack	25	Yes £ . Exempt	£
GP letter sent informing GP of supply			GP name:			
2	Varenicline 4 weeks		0.5mg 1mg	56	Yes £ . Exempt	£
DH monitoring form sent to SWYPFT			Treatment outcome recorded		Quit CO verified <input type="checkbox"/> Quit self report <input type="checkbox"/> Not Quit <input type="checkbox"/> Lost to follow up <input type="checkbox"/>	
3	Varenicline 4 weeks		0.5mg 1mg	56	Yes £ . Exempt	£
4	Varenicline 2 weeks		0.5mg 1mg or Titration pack	28 or 25	Not applicable for this supply	£
Service Commissioner letter sent			Supply of longer than 12 weeks will only be paid when letter has been submitted			
5	Varenicline 4 weeks		0.5mg 1mg	56	Yes £ . Exempt	£
6	Varenicline 4 weeks		0.5mg 1mg	56	Yes £ . Exempt	£
7	Varenicline 4 weeks		0.5mg 1mg	56	Yes £ . Exempt	£
Medication cost						£
Total prescription fees collected from patient						£
Medication cost minus prescription fees						
Total fee due to pharmacy						£

Declaration

I claim payment for the Varenicline supply as outlined above. I confirm that the information given on this form is true and complete. I understand that if I provide false or misleading information I may be liable to prosecution or civil proceedings. I understand that the information on this form may be provided to the Counter Fraud and Security Management Service, a division of the NHS Business Services Authority, for the purpose of verification of this claim and the prevention, detection and investigation of fraud.

Signed _____

Date _____

GPhC number _____

Pharmacy Stamp

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Client Assessment Form Guidance for Stop Smoking Advisors

The following form on must be completed by every patient

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 of 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 supplied NRT 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.

The PGD for Varenicline details the conditions where Varenicline treatment is not appropriate.

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 pharmacist.

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

In a week how many units would you drink? units
1 unit= half a pint, 1 unit = 125ml (small glass) of wine, 1 unit = single measure of a spirit

Past medical history

Do you have a history of feeling depressed, low in mood?	Yes	No
Have you ever been diagnosed with bipolar disorder?	Yes	No
Have you ever been prescribed medication for low mood, depressions or anxiety? e.g antidepressants	Yes	No
Have you ever been diagnosed with a seizure (fits) disorder?	Yes	No
Have you ever been diagnosed with an eating disorder?	Yes	No

Current medical history

During the last month, have you often been bothered by feeling down, depressed or hopeless?	Yes	No
During the last month, have you often been bothered by having little interest or pleasure in doing things?	Yes	No
Do you have reduced kidney function? (also called renal impairment)	Yes	No

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.

.....

.....

.....

.....

I understand that the pharmacist will inform my GP of the supply of Varenicline and the details that I have supplied.

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.

Client Declaration

EXEMPTION

I am eligible for free Varenicline under this service because I:

- B** 18 **and** in full time education
- C** Is 60 years of age or over
- D** Has a valid maternity exemption certificate
- E** Has a valid medical exemption certificate
- F** Has a valid prescription pre-payment plan
- G** Has a valid War Pension exemption certificate
- L** Is named on a current HC2 charges certificate
- X** Was prescribed free-of-charge contraceptives
- H** Gets Income Support (IS)*
- K** Gets **income based** Jobseeker's Allowance (JSA (IB))*
- M** Is entitled to, or named on, a valid NHS Tax Credit Exemption Certificate*
- S** Has a partner who gets Pension Credit guarantee credit (PCGC)*

***Give details of the person getting benefit, this may be your partner.**

Name _____

Date of birth _____ (clients under 18 are not able to access due to the PGD)

You will be asked to show proof that you do not have to pay prescription charges. If you do not have proof, you will still get your medicine supply but checks may be made later to confirm your eligibility.

I confirm proper entitlement to exemption and for the purposes of checking this, I consent to the disclosure of relevant information from this form to the NHS Counter Fraud and Security Management Service and Local Authorities.

The information I have supplied is correct to the best of my knowledge.

Client's
Signature:

Date:

Clients not exempt from prescription charges and will pay prescription charges as outlined in the treatment option section. A 12 week course will incur 3 prescription charges.

Treatment options under Varenicline PGD

Supply number	1 Initial Consultation	2	3	4	5	6	7
Length of supply	2 weeks	4 weeks	4 weeks	2 weeks	4 weeks	4 weeks	4 weeks
Number of tablets in supply	25	56	56	28	56	56	56
Prescription fee due	Yes	Yes	Yes	No	Yes	Yes	Yes
Usual course	Titration pack Days 1 – 3: 0.5 mg (white tablets) once daily Days 4 – 7: 0.5 mg twice daily	1 mg (light blue tablets) twice daily	1 mg (light blue tablets) twice daily	1 mg (light blue tablets) twice daily			
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.	Titration pack Days 1 – 3: 0.5 mg (white tablets) once daily Days 4 – 7: 0.5 mg twice daily	1 mg (light blue tablets) twice daily	1 mg (light blue tablets) twice daily	Titration pack in reverse Days 1 – 4: 0.5 mg twice daily Days 5 – 7: 0.5 mg (white tablets) once daily			

Supply number	1 Initial Consultation	2	3	4	5	6	7
Length of supply	2 weeks	4 weeks	4 weeks	2 weeks	4 weeks	4 weeks	4 weeks
Number of tablets in supply	25	56	56	28	56	56	56
Prescription fee due	Yes	Yes	Yes	No	Yes	Yes	Yes
<p>Clients who cannot tolerate Varenicline because of adverse effects, e.g. nausea, may have the dose temporarily or permanently lowered to 0.5mg twice daily as per SPC</p> <p>Any rationale for tapering doses must be documented in the Varenicline Client Record.</p>	<p>Titration pack Days 1 – 3: 0.5 mg (white tablets) once daily</p> <p>Days 4 – 7: 0.5 mg twice daily</p>	<p>1 mg (light blue tablets) twice daily</p> <p>OR</p> <p>0.5 mg (white tablets) twice daily</p>	<p>1 mg (light blue tablets) twice daily</p> <p>OR</p> <p>0.5 mg (white tablets) twice daily</p>	<p>1 mg (light blue tablets) twice daily</p> <p>OR</p> <p>0.5 mg (white tablets) twice daily</p>			
<p>Clients requesting a longer course may be supplied with an additional course of up to 12 weeks treatment at 1mg twice daily.</p> <p>Clients 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.</p> <p>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.</p> <p>Any rationale for additional treatment beyond the 12 weeks must be documented in the Varenicline Client Record.</p>	<p>Titration pack Days 1 – 3: 0.5 mg (white tablets) once daily</p> <p>Days 4 – 7: 0.5 mg twice daily</p>	<p>1 mg (light blue tablets) twice daily</p>	<p>1 mg (light blue tablets) twice daily</p>	<p>1 mg (light blue tablets) twice daily</p> <p>OR</p> <p>Titration pack in reverse Days 1 – 4: 0.5 mg twice daily</p> <p>Days 5 – 7: 0.5 mg (white tablets) once daily</p>	1 mg (light blue tablets) twice daily	1 mg (light blue tablets) twice daily	1 mg (light blue tablets) twice daily

Treatment supply record

Client details			
Full Name			
Address			
Postcode			
Telephone		Mobile	
Date of Birth			
Client ID number	Insert patient's PMR number		
GP Name			
GP surgery address			
Postcode			
Pharmacy name			
ODS code	F		
Pharmacist responsible for supply under PGD			
GPhC registration number			
Date client enrolled for PGD and client assessment form completed			
Date letter sent to GP <ul style="list-style-type: none"> • Complete letter on p17 • Copy letter and staple to back of this client record • Send letter to GP to be received within 1 week 			
Date client plans to stop smoking	Usually 1-2 weeks after starting Varenicline		
Date of last tobacco use	Transfer information from DH Gold monitoring form		
Date of 4 wk follow-up	Transfer information from DH Gold monitoring form		
Date DH monitoring form sent to SWYPFT			
Treatment outcome recorded	Quit CO verified <input type="checkbox"/> Quit self report <input type="checkbox"/> Not Quit <input type="checkbox"/> Lost to follow up <input type="checkbox"/>		

Initial supply- Two weeks

Date	
Supplying pharmacist	
GPhC number	

Checklist

	Completed the Client Assessment Form for Varenicline with the client
	Client signed the Client Assessment Form
	Set appropriate quit date with the client
	Checked current medication
	Confirmed client not pregnant, likely to become pregnant or breastfeeding
	Prescription fee paid or exemption confirmed
	Supply appropriate in line with PGD (exclusions, cautions, contraindications)
	Provide client with the contact number of the pharmacy and name of the pharmacist so that they can discuss any queries or report any problems/ side effects
	Set next Varenicline supply appointment
	Send letter to GP informing them of supply
	Record medication supply on PMR

Counselling points

	Client aware they should start taking Varenicline 1-2 weeks before they stop smoking
	Discuss possible side effects, actions client can take to manage side effects and note that side-effects should be reported to the pharmacist who supplied Varenicline
	Discuss when to immediately stop treatment - If client develops agitation, depressed mood, changes in behaviour or suicidal thoughts they should stop treatment and contact their GP/ doctor immediately
	Inform client of 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 possibility of withdrawal symptoms (with an increase in irritability, urge to smoke, depression, and/or insomnia in up to 3% of patients).
	Inform client 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.
	Explain how to take Varenicline starter pack
	Discuss mode of action of Varenicline and that Varenicline does not remove all temptation to smoke, but it does make abstinence easier
	Explain Varenicline is to be taken continuously as a course for 12 weeks
	Client asked to read the Patient Information Leaflet supplied with the Varenicline

Medication supply

Drug	Quantity	Strength	Dose	Batch	Expiry	Script fee or exemption code?
Varenicline						

I have been provided with a two weeks supply of Varenicline.

I am exempt from prescription charges and have completed the declaration on p5

I have paid a charge of **Signed (Client)**..... **Date**

Transfer supply to summary sheet p3

Second supply- Four weeks

Date	
Supplying pharmacist	
GPhC number	

Checklist	
	Confirm no change in answers to Client Assessment Form
	Discuss any side effects
	Client has not developed any signs of agitation, depressed mood, suicidal thoughts or other serious mood changes (client to be referred to GP for prompt medical advice)
	Confirmed client not pregnant or likely to become pregnant
	No new contraindications
	Confirm client wishes to continue with treatment
	Confirm smoking status and that the client is continuing to try and quit smoking
	Prescription fee paid or exemption re-confirmed
	Supply appropriate in line with PGD (exclusions, cautions, contraindications)
	Set next Varenicline supply appointment

Counselling points	
	If client develops agitation, depressed mood, changes in behaviour or suicidal thoughts they should stop treatment and contact their GP/ doctor immediately
	Any side-effects should be reported to the pharmacist who supplied Varenicline
	Explain how to take Varenicline dose

Nausea and vomiting

Mild nausea is common, typically occurring 30 minutes after taking a tablet and lasting for about 30 minutes. Moderate or severe persisting nausea or vomiting is unusual and the adviser will discuss options with the patient:

1. To reduce the dose to 0.5mg twice daily as per SPC
2. Cessation of varenicline and swapping to another pharmacotherapy.

Medication supply						
Drug	Quantity	Strength	Dose	Batch	Expiry	Script fee or exemption code ¹ ?
Varenicline						

<p>I have been provided with a four weeks supply of Varenicline.</p> <p><input type="checkbox"/> I am exempt from prescription charges and have completed the declaration on p5</p> <p><input type="checkbox"/> I have paid a charge of</p>	
<p>Signed (Client).....</p>	<p>Date</p>

Transfer supply to summary sheet p3

¹ Code from exemption list on p5

Third supply- Four weeks

Date	
Supplying pharmacist	
GPhC number	

Checklist

	Confirm no change in answers to Client Assessment Form
	Discuss any side effects
	Client has not developed any signs of agitation, depressed mood, suicidal thoughts or other serious mood changes (client to be referred to GP for prompt medical advice)
	Confirmed client not pregnant or likely to become pregnant
	No new contraindications
	Confirm client wishes to continue with treatment
	Confirm smoking status and that the client is continuing to try and quit smoking
	Confirm with smoking advisor that 4 week DH monitoring form has been completed and sent to SYWPFT. Copy of form to be attached to this record.
	Prescription fee paid or exemption re-confirmed
	Supply appropriate in line with PGD (exclusions, cautions, contraindications)
	Set next Varenicline supply appointment

Counselling points

	If client develops agitation, depressed mood, changes in behaviour or suicidal thoughts they should stop treatment and contact their GP/ doctor immediately
	Any side-effects should be reported to the pharmacist who supplied Varenicline
	Explain how to take Varenicline dose

Nausea and vomiting

Mild nausea is common, typically occurring 30 minutes after taking a tablet and lasting for about 30 minutes. Moderate or severe persisting nausea or vomiting is unusual and the adviser will discuss options with the patient:

1. To reduce the dose to 0.5mg twice daily as per SPC
2. Cessation of varenicline and swapping to another pharmacotherapy.

Medication supply

Drug	Quantity	Strength	Dose	Batch	Expiry	Script fee or exemption code?
Varenicline						

I have been provided with a four weeks supply of Varenicline.

- I am exempt from prescription charges and have completed the declaration on p5
- I have paid a charge of

Signed (Client)..... **Date**

Transfer supply to summary sheet p3

Fourth supply- Two weeks

Date	
Supplying pharmacist	
GPhC number	

Checklist	
	Confirm no change in answers to Client Assessment Form
	Discuss any side effects
	Client has not developed any signs of agitation, depressed mood, suicidal thoughts or other serious mood changes (client to be referred to GP for prompt medical advice)
	Confirmed client not pregnant or likely to become pregnant
	No new contraindications
	Confirm client wishes to continue with treatment
	Confirm smoking status and that the client is continuing to try and quit smoking
	Supply appropriate in line with PGD (exclusions, cautions, contraindications)

Counselling points	
	If client develops agitation, depressed mood, changes in behaviour or suicidal thoughts they should stop treatment and contact their GP/ doctor immediately
	Any side-effects should be reported to the pharmacist who supplied Varenicline
	Explain how to take Varenicline dose
	Inform client of possibility of withdrawal symptoms (with an increase in irritability, urge to smoke, depression, and/or insomnia in up to 3% of patients).

Clients who report experiencing a strong urge to restart smoking can 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.

Medication supply						
Drug	Quantity	Strength	Dose	Batch	Expiry	Script fee?
Varenicline						NA

<p>I have been provided with a two weeks supply of Varenicline.</p> <p>No charge applicable for this supply</p> <p>Signed (Client)..... Date</p>
--

Transfer supply to summary sheet p3

Treatment over 12 weeks

Most clients who stop smoking and remain abstinent will stay on Varenicline for 12 weeks only.

Clients requesting a longer course may be supplied with an additional course of up to 12 weeks treatment at 1mg twice daily.

Clients 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.

When additional treatment courses are supplied the service commissioner must be informed in every instance.

A letter is attached for this purpose.

DO NOT send any patient identifiable information into the PCT.

Any rationale for additional treatment beyond the 12 weeks must be documented. This can be achieved by retaining a copy of the letter on p16.

As supply beyond 12 weeks is uncommon, treatment supply notes have not been provided for supplies over 12 weeks. To record supply beyond 12 weeks copies of p13, the third supply sheet should be made and attached to the end of this document.

For patients not exempt from prescription charges, a prescription fee will be levied for each 4 week supply.

A maximum of 12 further weeks of Varenicline can be supplied in 4 weeks aliquots.

5th supply – 4 weeks

6th supply – 4 weeks

7th supply – 4 weeks

Letter to Service Commissioner

To be sent to Paul Butcher for every client where the supply exceeds 12 weeks
Copy to be attached to Varenicline Client Record

Pharmacy name:
Pharmacy Address:

Postcode:
Telephone:

Paul Butcher
Deputy Director of Public Health
Calderdale Primary Care Trust
4th Floor
F Mill
Dean Clough
Halifax
HX3 5AX

Date:

Dear Mr Paul Butcher,

Varenicline supply

I am writing to you to inform you that one of my clients requires supply of Varenicline beyond the 12 week standard course.

The rationale for this client requiring treatment beyond 12 weeks is:

Client ID number	Insert patient's PMR number
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NB: **Do not** include any patient identifiable information such as name, date of birth

Yours sincerely,

Pharmacist

Pharmacist Contact Details:

Name:
Address:

Contact Number:

GP Letter

To be sent to GP for every client

Copy to be attached to Varenicline Client Record

Pharmacy name:

Pharmacy Address:

Postcode:

Telephone:

GP details:

Date:

Varenicline

Ref: Your patient

Date of Birth

I am writing to inform you that your patient has decided to stop smoking and following an assessment has been supplied Varenicline via a Patient Group Direction. Varenicline is being supplied as part of a structured Stop Smoking Service.

From information supplied by the patient an assessment has been made which included past mental health, current mental health and medication history and no contraindications to treatment with Varenicline were identified.

If you are aware of any reasons why this client should not be supplied with Varenicline please contact me as below.

Yours sincerely

Pharmacist

Pharmacist Contact Details:

Name:

Address:

Contact Number: