



This Patient Group Direction (PGD) must only be used by registered community pharmacists who have been named and authorised by their organisation to practice under it. The PGD must only be used in conjunction with a local authority commissioned service specification for Stop Smoking Services. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction HCC202012
for the supply of varenicline
by registered community pharmacists for
Stopping Smoking in Hertfordshire

Version number: 1.1a

Version 1.1

Development and review of PGD on renewal. Changes since previous version:

1. Change of PGD Reference and version number
2. Change of valid to and from dates
3. Updated by members of the PGD working group
4. Inclusion criteria updated to include clear definition of quit date
5. References checked and updated
6. Content updated from SPC and BNF
7. Algorithm updated

Version 1.1a

1. Appendix 5 (Registered Pharmacist Authorisation Sheet) amended so that a senior person with designated authority within the provider organisation can sign as authorising manager.
2. Additional Requirements amended so the signed Appendix 5 is retained by the provider organisation where it is readily available and no longer needs to be returned to Hertfordshire Health Improvement Service

| | Name | Job title and organisation |
|----------------------------------|---------------|--|
| Members of the PGD working Group | Alison Walsh | Health Improvement Manager Public Health |
| | Linda Mercy | Senior Doctor HCC |
| | Helen Musson | Executive Officer, Hertfordshire Local Pharmaceutical Committee |
| | Purvi Barchha | Community Pharmacist |
| | David Conrad | Chair of the PH AGG (Public Health Consultant) |
| | Dipti Patel | Clinical Governance, Primary Care and Pharmacy Lead, Wellbeing and Public Health, Essex County Council |

PGD development group

PGD authorisation

| Name | | Job title and organisation | Signature | Date |
|---|--------------|--|--|------------|
| Health Improvement Manager | Alison Walsh | Health Improvement Manager, Public Health, Hertfordshire County Council |  | 03/09/2020 |
| Pharmacist | Dipti Patel | Clinical Governance, Primary Care and Pharmacy Lead, Wellbeing and Public Health, Essex County Council |  | 03/09/2020 |
| Person signing on behalf of Public Health | Linda Mercy | Senior Doctor, Hertfordshire County Council |  | 08/09/2020 |

| Requirements of registered community pharmacists working under the PGD | |
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| Qualifications and professional registration | Qualified community pharmacist who is registered with the GPhC AND accredited to use the Patient Group Direction (PGD) by Hertfordshire Health Improvement Service. |
| Initial training | <p>The pharmacist must be aware of the service specification standards for providing a stop smoking service AND training must include attendance (face to face or virtual) at the Varenicline Accreditation Support Event and ensure they are competent to deliver smoking cessation interventions.</p> <p>The community pharmacy must have a current contract with Hertfordshire County Council Public Health Service to deliver stop smoking services. There must be a Level 2 trained stop smoking advisor delivering stop smoking support to the client, but this does not need to be the pharmacist accredited to supply varenicline under this PGD.</p> |
| Competency assessment | <p>The Pharmacist should have achieved the competency levels specified in the NICE Competency Framework for Health Professional using Patient Group Directions.</p> <p>https://www.nice.org.uk/guidance/mpg2/chapter/Recommendations#using-patient-group-directions</p> |
| Ongoing training and competency | <p>The pharmacist should be aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual pharmacist to keep up to date with continued professional development and to work within the limitations of individual practice.</p> <p>It is essential that pharmacists involved in PGDs in any way have adequate indemnity insurance to cover the tasks they are undertaking. These apply equally to those involved in the drawing up of PGDs, accuracy checking, reviewing, those responsible for signing them (authorising), and those responsible for administering and / or supplying medicines under a PGD.</p> |
| Additional requirements | <p>The superintendent pharmacist must maintain records and names of individuals who are competent and signed up to operate the PGD in the pharmacy. For businesses with more than one pharmacy, this must be maintained for each pharmacy premise in the group.</p> <p>The pharmacy must have a standard operating procedure (SOP) in place for all aspects of the service.</p> <p>The pharmacy contractor or superintendent pharmacist must complete the authorisation form (appendix five). One copy should be given to each participating Pharmacist. The original signed copy should be retained and be easily available within the Community Pharmacy.</p> |

| CLINICAL CONDITION | |
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| Clinical condition or situation to which this PGD applies | Nicotine dependent smokers over the age of 18 who are accessing Community Pharmacy Stop Smoking Services commissioned by Hertfordshire County Council for help to stop smoking. The supply of varenicline must be part of a treatment programme combined with behavioural support. |
| Inclusion criteria | <ul style="list-style-type: none"> • Dependent tobacco users identified as sufficiently motivated to quit smoking with varenicline with a set quit date between 7-14 days. • Clients aged 18 and over. • The client agrees to receive behavioural support as per the Service Specification Algorithm outlined in the public health service specification to deliver stop smoking services (Appendix 1). • A full medical history is taken and documented to ensure there are no contraindications for treatment with varenicline (see criteria for exclusion and referral). • An electronic record of the client assessment form is completed • Client has consented for information to be shared with their GP, Hertfordshire Health Improvement Service and anonymised data shared with NHS Digital and recorded on client's clinical record on PharmOutcomes or other database approved by Hertfordshire County Council for this purpose. • Clients who are taking other medication that need dose adjusting on quitting or resuming smoking should agree to keep their GP informed of their smoking status, in addition to understanding that the pharmacist may share this information with their GP. |
| Exclusion criteria | <ul style="list-style-type: none"> • Tobacco users not sufficiently motivated to quit smoking. • Hypersensitivity to varenicline or any of its excipients. • Clients with current (or a history of) serious psychiatric illness such as schizophrenia, bipolar disorder and major depressive disorder. • Client under 18 years of age. • Clients over 65 years of age if renal status cannot be established. • Pregnant (or if there is a likelihood of being pregnant) or breastfeeding women. • Clients with a history of renal impairment. • Clients taking cimetidine with reduced renal function. • Clients with epilepsy or history of seizures. • Clients with a history of myocardial infarction or at risk of myocardial infarction. • Where there is no valid consent. • Client not registered with a GP. • Client is unable to supply sufficient information regarding possible exclusions to enable a decision to supply to be |

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| | <p>made safely.</p> <p>Refer to the latest version of the SPC https://www.medicines.org.uk/emc/product/266/smpc</p> |
| <p>Drug interactions</p> | <p>Based on varenicline characteristics and clinical experience to date, the drug has no meaningful drug interactions.</p> <p><u>Concomitant medication & smoking cessation</u> Cigarette smoking increases the metabolism of some medicines by stimulating the hepatic enzyme CYP1A2. When smoking cessation is successful, the dose of some of these drugs may need to be reduced, & regular monitoring for any increase in adverse effects is advised. These drugs include:</p> <ul style="list-style-type: none"> • Clozapine • Olanzapine • Insulin • Warfarin • Theophylline • Chlorpromazine • Methadone <p>Please note: This list is not exhaustive and further clarification using relevant reference sources, cross referencing the client's current medication profile, should be made by the pharmacist supplying any smoking cessation product in accordance with the pharmacy contractor's procedures.</p> <p>Clients on any medicine affected by taking varenicline/stopping smoking should be informed of the need to keep their medical prescriber informed of their smoking status.</p> |

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| <p>Side effects</p> | <p>Common or Very Common (from SPC very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$))</p> <ul style="list-style-type: none"> • Nausea is the most common side effect (about 30% of clients). This can be reduced by taking the tablet after food and with a full glass of water • Headache • Appetite changes • Weight increase • Dry mouth /taste disturbances • Drowsiness • Dizziness • Abnormal thinking • Mood swings • Nasopharyngitis • Bronchitis, sinusitis • Abnormal dreams, insomnia • Somnolence • Dyspnoea, cough • Gastroesophageal reflux disease • Vomiting • Constipation • Diarrhoea • Abdominal distension • Abdominal pain • Toothache • Dyspepsia • Flatulence • Rash, pruritus • Arthralgia, myalgia, back pain • Chest pain, fatigue <p>NB: for more information about less common and rare side effects please refer to the latest version of the SPCs.</p> <p>Important Safety Information</p> <p>1. Depressed mood may be a symptom of nicotine withdrawal. Depression, rarely including suicidal ideation and suicide attempt, has been reported in clients while undergoing a smoking cessation attempt. These symptoms have also been reported when attempting to quit smoking with varenicline.</p> <p>2. MHRA/CHM advice on suicidal behaviour and varenicline – Clients should be advised to discontinue treatment immediately and seek prompt medical advice if they develop agitation, depressed mood, or suicidal thoughts (over and above those detailed in point 1 above).</p> <p><u>Effects on ability to drive and use machines</u></p> <p>Varenicline may have minor or moderate influence on the ability to drive and use machines. Varenicline may cause dizziness,</p> |
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| | somnolence and transient loss of consciousness, and therefore may influence the ability to drive and use machines. Patients are advised not to drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether this medicinal product affects their ability to perform these activities. |
| Arrangements for referral for medical advice | Know the referral pathway into Hertfordshire Health Improvement Service and how to contact the client's GP for medical advice. |
| Action to be taken if client excluded | Offer a referral to their GP or to Hertfordshire Health Improvement Services to discuss varenicline treatment if deemed appropriate. Discuss nicotine containing products as an alternative treatment option. Document action in notes. |
| Action to be taken if client declines treatment | Clients are free to decline treatment as motivation is required to successfully quit smoking. Document action in notes. Offer tobacco harm reduction advice, behavioural support, and advise on use of electronic cigarettes or licensed NRT. |
| Additional guidance for client aged under 18 | Discuss alternative age-appropriate products and behavioural support. Document action in notes. |

| DETAILS OF THE MEDICINE | |
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| Name, form and strength of medicine | Varenicline 0.5 mg film coated tablets Varenicline 1 mg film coated tablets |
| Legal category | POM Prescription Only Medicine |
| Indicate any off-label use (if relevant) | No off-label use |
| Route of administration | Oral |
| Dose and frequency | <p>Smokers should set a date to stop smoking. Treatment with varenicline should commence 1 to 2 weeks before this date using a titration pack.</p> <p>Day 1-3 Take one 0.5mg (white) tablet once daily.</p> <p>Day 4-7 Take one 0.5mg tablet twice daily, once in the morning and once in the evening, at about the same time each day.</p> <p>Day 8 –up to a further 11 weeks or earlier if unsuccessful. Take one 1mg (blue) tablet twice daily, once in the morning and once in the evening, at about the same time each day.</p> <p>Tablets should be swallowed whole with plenty of water and with food.</p> <p>Clients who cannot tolerate the side effects (principally nausea) of varenicline, but are still motivated to continue treatment, may have their dose lowered temporarily or permanently to 0.5 mg twice daily (BNF)</p> <p>Dose tapering In clients with a high risk of relapse, dose tapering may be considered at the end of the standard 12 weeks of treatment Lower dose to end of treatment (normally 12 weeks in total): 0.5 mg (white tablets) twice daily</p> |

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| <p>Quantity to be administered and/or supplied</p> | <p>1st supply – 2 weeks (initiation pack containing 11 x 0.5mg tablets & 14 x 1mg tablets)</p> <p>2nd supply – 2 weeks (1mg tablets x 28)</p> <p>3rd supply – 2 weeks (1mg tablets x 28)</p> <p>4th supply – 2 weeks (1mg tablets x 28)</p> <p>5th supply – 2 weeks (1mg tablets x 28)</p> <p>6th supply – 2 weeks (1mg tablets x 28)</p> <p>Where the dose is reduced to 0.5mg twice a day a pack of 28 tablets to be supplied as above. Each supply must be labelled and include a patient information leaflet (PIL). Maximum treatment period is a 12-week course</p> |
| <p>Management of care</p> | <ul style="list-style-type: none"> • An agreed quit date should be recorded at the time of supplying varenicline. This should be preferably 7-14 days after initiation of treatment. • At the end of the treatment course dose tapering (reducing to 1mg per day during last week) can be recommended if client is concerned about suddenly stopping medication. • Clients should be assessed for any signs of changes in mental health status especially in relation to depressed mood, agitation and extreme thoughts at every visit to the pharmacy. |

Advice & information to clients

- Specific product advice on dosage, method of administration and side effects.
- Seek consent to access Summary Care Record (SCR)
- Contact details for Pharmacy Stop Smoking Service and Hertfordshire Health Improvement Service.
- Varenicline information leaflet (attached for information in Appendix 3).
- Attend pharmacy weekly for 6 weeks, then every 2 weeks until the end of the course.
- Contact the client weekly and at 4 weeks assess and record quit status and CO validate where possible
- Advise on common nicotine withdrawal symptoms and common side effects of varenicline.
- Advise clients about the possible emergence of depressive symptoms when undertaking a smoking cessation attempt and advise them accordingly. Clients should be advised to seek medical advice if symptoms occur.
- If client suffers from excessively depressed mood (beyond normal withdrawal symptoms from smoking cessation) stop tablets immediately and inform GP and pharmacist.
- Get emergency medical help right away if you have symptoms of heart attack or stroke.
- It is important that the client be encouraged to declare any current or recent history of mental illness (see information on exclusion criteria). Pharmacists should be aware of the possible stigma associated with the declaration of such conditions and therefore ensure that the client has sufficient privacy during the initial consultation to facilitate such conversations.
- It is important to make sure that the client understands the following points about varenicline:
 1. It works by acting on the parts of the brain which are affected by nicotine in cigarettes.
 2. It does not remove all the temptation to smoke, but it does make abstinence easier (it reduces the severity of tobacco withdrawal symptoms such as cravings to smoke, irritability, poor concentration and low mood).
 3. Nausea affects one third of clients taking varenicline, it often diminishes gradually over the first few weeks, and most clients tolerate it without problems. Nausea can be reduced if the product is taken with food.

The following general advice should also be given:

- Follow-up and how to obtain further supplies.
- Varenicline may cause drowsiness. If affected, the client should be advised not to drive or operate machinery.
- It is important the client takes the medication regularly and at the same time each day.

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| | <ul style="list-style-type: none"> • If the client forgets to take a dose, they should take it as soon as they remember, but at least 8 hours should elapse before the next dose is taken. If it is within 3-4 hours before the next dose, the missed tablet should not be taken. • At the end of treatment, discontinuation of varenicline has been associated with an increase in irritability, urge to smoke, and/or insomnia in up to 3% of clients. The pharmacist should inform the client accordingly and discuss or consider the need for dose tapering. |
| Adverse Reactions and their Management | All adverse drug reactions must be documented in the patient record and reported immediately to the client's GP. Clients should be advised to discontinue treatment and seek prompt medical advice if they develop agitation, depressed mood or suicidal thoughts beyond what is expected during a normal smoking cessation attempt. |
| Reporting procedure of Adverse Reactions | Serious adverse reactions (e.g. anaphylaxis) should be reported. Should such a reaction occur the pharmacist must follow their reporting procedures, inform the client's GP and immediately complete an Incident Form. The incident should be reported to the Medicines and Healthcare Products Regulation Agency (MHRA) using the Yellow Card System. Yellow Cards are available in the BNF as well as online https://yellowcard.mhra.gov.uk/ Serious adverse reactions must also be reported to Hertfordshire Health Improvement Service. |
| Additional Facilities | Pharmacies must have a suitable consultation room that meets the specification for provision of NHS advanced services, as described in the Public Health Contract with community pharmacy contractors. All medicines dispensed under this PGD must be procured and stored according to the requirements of the Medicines Act 2012. Details of the product(s) supplied, invoices, and prescription charges collected must be recorded. |
| Special Considerations / Additional Information | For a comprehensive list of all warnings, cautions and potential adverse reactions, refer to the current British National Formulary (BNF) and the current Summary of Product (SPC) Characteristics. |
| Arrangements for handling, security, storage labelling | <ul style="list-style-type: none"> • Store in a dry place, at room temperature (below 30°C), away from direct sunlight (protect from light). • All medicines supplied to a client under PGD must comply with the EC labelling and leaflet directive, i.e. must be fully labelled and an appropriate Patient Information Leaflet (PIL) supplied. |
| Records | <ul style="list-style-type: none"> • Date of supply • Client assessment form (Appendix 2) must be completed in full and signed by pharmacist and client or completed |

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| | <p>electronically and verbally agreed by the client ensuring inclusion criteria have been met</p> <ul style="list-style-type: none"> • Dose and quantity supplied • Manufacturer / Brand • Batch number • Expiry date • Any adverse reactions experienced • Advice given • The GP letter (Appendix 4) must be completed and sent securely to the client's GP practice if the GP is not notified via PharmOutcomes <p>Records must be kept securely in compliance with the Data Protection Act 2018 (includes GDPR) and Caldicott guidelines. Records must be transferred electronically to the secure database approved by Hertfordshire County Council for this purpose.</p> <p>Recordkeeping must comply with NHS recordkeeping https://digital.nhs.uk/records-management-code-of-practice-for-health-and-social-care-2016</p> |
| Consent | <ul style="list-style-type: none"> • A record of consent must be obtained in accordance with Hertfordshire County Council's Public Health Contract with community pharmacy contractors. • Clients must be informed that information relating to the supply of varenicline under a PGD will be shared with Hertfordshire Health Improvement Service and will be shared with their GP. |

KEY REFERENCES

| | |
|---|---|
| 1 | Nice; Varenicline for smoking cessation TA123 https://www.nice.org.uk/guidance/TA123 [Accessed 14th July 2020] |
| 2 | NICE Stop smoking interventions and services https://www.nice.org.uk/guidance/ng92 [Accessed 14th July 2020] |
| 3 | Summary of Product Characteristics https://www.medicines.org.uk/emc/product/266/smpc Last updated on EMC on 23 rd July 2019 [Accessed 14 th July 2020] |
| 4 | BNF online [Accessed 13 th July 2020] https://bnf.nice.org.uk/drug/nicotine.html https://bnf.nice.org.uk/drug/varenicline.html |
| 5 | NHS Local Stop Smoking Services: Service and delivery guidance 2014 http://www.ncsct.co.uk/publication_service_and_delivery_guidance_2014.php [Accessed 13 th July 2020] |
| 6 | Hertfordshire County Council Consent Policy https://www.hertfordshire.gov.uk/about-the-council/legal/privacy-policy/privacy-policy.aspx [Accessed 14th July 2020] |
| 7 | NICE Good Practice Guidance on Patient Group Directions and the Competency framework for healthcare professionals using Patient Group Directions https://www.nice.org.uk/guidance/mpg2 last updated March 2017 [Accessed 14 th July 2020] |
| 8 | What medicines need dose adjustment when a patient stops smoking? – UKMi Medicines Q&As http://www.oxfordhealthformulary.nhs.uk/docs/Which%20medicines%20need%20dose%20adjustment%20when%20a%20patient%20stops%20smoking%20UKMI%20QA%20Aug%202012.pdf [Accessed 14 th July 2020] |
| 9 | Hertfordshire Guidance: Stop smoking medication October 2019- September 2021 Stop smoking (professional) Hertfordshire County Council www.hertfordshire.gov.uk [Accessed 14 th July 2020] |

LIST OF APPENDICES

Appendix 1 - Service Specification Algorithm 2020

Appendix 2 - Client Assessment Form

Appendix 3 - Varenicline Information Leaflet

Appendix 4 – GP letter

Appendix 4 - GP letter Appendix 5 - Pharmacist Authorisation Form

Appendix 1: Service Specification Algorithm (2020)

FIRST CONTACT:

Service user presents for help to stop smoking at a local pharmacy or has been identified/referred for help.

Explain service and expectation of weekly support for best chance of success, provide booklet on stopping smoking and make first appointment. Consider referral to specialist service if service user is pregnant, has a mental health condition or complex needs, or has not quit successfully with your service previously. Explain commitment is for at least 4 weeks following quit date. If service user not ready to quit, ensure they are welcomed to access service at later date and give harm reduction advice, including advice on e-cigarettes.

Medication:

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

<http://www.oxfordhealthformulary.nhs.uk/searchresults.asp?SearchVar=smoking&Submit=Search>

for details of medicines which may need dose adjusting

FIRST APPOINTMENT: Usually pre-quit (30 mins)

Establish service user relationship

CONSENT: complete on PharmOutcomes

Note relevant medical history/medication.

Assess smoking history and current dependency (Fagerstrom Test)

Assess motivation and confidence to quit

Explain CO monitoring and record reading (use as motivational tool)

Negotiate AND set quit date and discuss planning for it

Provide literature or website information: www.nhs.uk/smokefree

Discuss behaviour change/breaking the habit

Discuss withdrawal symptoms and coping mechanisms

Discuss all medication options approved by NICE, in line with local guidelines and patient choice, facilitate supply, explain use, and complete clinical record.

Make next appointment or follow up any DNAs

Complete all mandatory fields on PharmOutcomes

Advise service user that evaluation form will be sent to them via text message

If SBTO advice service user to book 8-week appointment with HHIS*

NRT option:

Provide Voucher code for NRT(maximum 2 weeks supply) or advise to purchase alternative NRT

Varenicline: Advisor

recommends varenicline or bupropion within NICE guidance and Hertfordshire Guidance: Stop smoking medication and the product's SPCs. Provider sends electronic prescription request to GP or provides varenicline under the PGD if pharmacist accredited.

APPOINTMENTS 2, 3 and 4: (10-15 minutes on or shortly after quit date and each and every following week)

Assess progress so far - congratulate any constructive behaviour change/efforts;

Discuss any lapses or barriers to quitting/difficulties to be overcome

Confirm quit date. Reinforce 'Not One Puff Rule' (NOPE)

Take CO reading to use as a motivator

Monitor use of medication – ensure adequate use and monitor side effects (give advice, adjust dose or change medication if severe adverse effects)

Ensure adequate medication until next appointment or later if POM)

Complete clinic notes on PharmOutcomes database

Discuss withdrawal symptoms and coping mechanisms

Build on repertoire of coping strategies and identify and help patient overcome any perceived obstacles

Follow up service users who have failed to attend appointments

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

Assess progress so far - quit or not quit at this four-week follow-up appointment

Congratulate success if appropriate and encourage staying stopped

For those who haven't quit, suggest returning for another course when ready

Complete CO reading (must be less than 10ppm to validate non-smoking status)

Service user must be smoke free for the last 14 days of the 28 days since setting a quit date

Complete Quit Status on PharmOutcomes for monitoring and payment purposes

Complete clinical record

Identify risks to staying stopped and ensure patient empowered to access service in future without fear of failure if relapse occurs.

Agree additional support for complex service users or refer to HHIS.

PGD reference HCC2020/2 Version 1.1a

Valid from: 1 December 2020
Ensure sufficient supply of NRT, varenicline or bupropion to complete full course of medication

Expiry date: 30 November 2023
For queries contact: Hertfordshire Health Improvement Service* (HHIS) on 01442 453071 or email: HealthImprovementService@hertfordshire.gov.uk

APPENDIX 2

Varenicline Client Assessment Form

Past/current medical history

1. Do you have a history of depression or other psychiatric disorder?

2. Have you been prescribed medication for low mood, depression or anxiety?

3. Do you have a history of kidney disease, reduced kidney function or kidney impairment?

4. Have you ever been diagnosed with epilepsy, seizures or fits?

5. Do you have heart disease or are you at increased risk of heart disease or have you ever had a heart attack?

6. Are you breastfeeding, pregnant or could you possibly be pregnant?

7. Have you an allergy to varenicline or any of the ingredients in the tablets?

8. Have you any allergies?

9. What medicines are you taking?

Varenicline Client Assessment Form (continued)

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| Client Name: | | | | |
| | Drug supplied | Client signature | Pharmacist signature | Date |
| 1 st supply | 2 weeks (Imp. Pack 11x0.5mg & 14x1mg) | | | |
| 2 nd supply | 2nd supply (1mg x 28) | | | |
| 3 rd supply | 3rd supply (1mg x 28) | | | |
| 4 th supply | 4th supply (1mg x 28) | | | |
| 5 th supply | 5th supply (1mg x 28) | | | |
| 6 th supply | 6 th supply (1mg x 28) | | | |

NB: Amend if 0.5mg supplied due to side effects

I confirm that the information provided is a true reflection and allows my community pharmacist to provide me with the most appropriate, safe, advice and treatment for me.

I consent that my information may be shared with my GP, Hertfordshire Health Improvement Service, and anonymised data shared with NHS Digital.

I consent that the pharmacy may view my Summary Care Record to confirm full medication and condition history

Verbal confirmation that the information provided is correct and consent may be given and recorded electronically.

Signed by client: _____

APPENDIX 3

Varenicline Patient Information Leaflet (Summary for information only)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

This is to be read in conjunction with the Patient Information Leaflet supplied with the medicine

Varenicline is a non-nicotine drug that is used to help people stop smoking. The drug mimics the effect of nicotine on the body and is thought to work by both reducing the urge to smoke and the pleasurable effects of smoking whilst also relieving withdrawal symptoms. It is not a magic cure and you will still need a lot of determination to stop smoking and support from your local NHS Stop Smoking clinic.

You will start taking varenicline before you stop smoking and stop smoking between day 8 to 14. You take 0.5mg once daily on days 1-3, then 0.5mg twice daily on days 4-7, then 1mg twice a day for the next 11 weeks. It is recommended that you swallow the tablets whole with water. Having food as well is a good idea to prevent nausea. The course of treatment is for 12 weeks:

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| Days 1-3 | 0.5mg once daily |
| Days 4-7 | 0.5mg twice daily |
| Day 8 and for a further 11 weeks | 1mg twice daily |

Missed Dose

If you forget to take varenicline, do not take a double dose to make up for the one you missed. It is important you take the medication regularly and at the same time each day.

If you have forgotten to take a dose, take it as soon as you remember but at least 8 hours must elapse before the next dose is taken. If, it is within 3-4 hours before your next dose, do not take the tablet that you have missed.

As with all medicines, varenicline is associated with certain side effects. These should be carefully weighed up against the known health benefits of stopping smoking. Varenicline may not be suitable for all people who wish to stop smoking and it is important that you discuss your suitability for varenicline treatment with your pharmacist or GP who will be familiar with your medical history.

Do not drive or operate machinery until you are sure how varenicline affects you.

Side Effects (SPC patient leaflet)

Very Common may affect more than 1 in 10 people

- o Inflammation of the nose and throat, abnormal dreams, difficulty sleeping, headache,
- o Nausea

Common may affect up to 1 in 10 people

- o Chest infection, inflammation of the sinuses
- o Increased weight, decreased appetite, increased appetite
- o Sleepiness, dizziness, changes in the way things taste
- o Shortness of breath, cough
- o Heartburn, vomiting, constipation, diarrhoea, feeling bloated, abdominal pain, toothache, indigestion, flatulence, dry mouth
- o Skin rash, itching
- o Joint ache, muscle ache, back pain
- o Chest pain, tiredness

Please also read the leaflet that comes with the tablets for the less common side effects. Not everyone will experience side effects, but if you experience a side effect that concerns you, please consult your pharmacist or GP.

Varenicline is not suitable for:

People who are hypersensitive to varenicline
Young people under 18
Pregnant women/breast feeding women
People with severe renal disease

Cardiovascular Disease

New or worsening heart and blood vessel problems have been reported primarily in people who already have cardiovascular problems. Tell your doctor if you have any changes in symptoms during treatment with varenicline. Get emergency medical help right away if you have symptoms of heart attack or stroke.

Depression

Depression, suicidal thoughts and behaviour as well as suicide attempts have been reported in people taking varenicline in post marketing experience. If you experience anxiety, depression or suicidal thoughts whilst taking varenicline, you **must** stop taking it and contact your GP or nurse immediately.

Epilepsy/Seizures

Some people have reported seizures (fits) while taking varenicline. Inform your pharmacist if you have ever experienced epilepsy or fits.

Interactions with other medicines

Varenicline has no clinically meaningful drug interactions.



APPENDIX 4 GP LETTER

Pharmacy Stamp

Date:

Patient information regarding the supply of varenicline (Champix) by an accredited pharmacist for stopping smoking in Hertfordshire under PGD HCC201812 or PGD HCC202012

Dear Doctor,

Re: Name.....

D.O.B.....

Address.....

In conjunction with Patient Group Direction HCC201812 or HCC 202012 for the supply of varenicline by registered community pharmacists for Stopping Smoking in Hertfordshire, this patient has been assessed as meeting the criteria for the supply of varenicline by the accredited pharmacist named below.

A starter pack (11 x 0.5mg and 14 x 1mg) has been supplied to this patient

All the treatment options have been discussed with this client and they have been assessed as suitable for varenicline.

The patient has completed a varenicline assessment form and from the information provided, they do not meet any of the exclusion criteria listed below.

Table with 2 columns listing exclusion criteria for varenicline supply, such as 'Not motivated to quit smoking' and 'Under 18 years of age'.

This patient will be supported by the pharmacy stop smoking service throughout the 12-week course of varenicline which will be supplied under this PGD. If you have any concerns about this patient receiving varenicline, please inform the pharmacy as soon as possible.

Yours faithfully,

Signed:

Print name:

The PGD may be accessed here: http://www.hertsipc.org.uk/public-health/hertfordshire-stop-smoking-service/

APPENDIX 5 - Registered Pharmacist Authorisation Sheet

PGD No HCC202012 – For the supply administration of varenicline by community pharmacists commissioned by Hertfordshire County Council and signatories to the PGD

Valid from: 1st December, 2020

Expiry: 30th November, 2022

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

Registered Pharmacist

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.

| Name | Designation | Date attended local Public Health Varenicline PGD training | Signature | Date |
|------|-------------|--|-----------|------|
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Authorising manager

I confirm that the registered pharmacists named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of:

Pharmacy name

F Code:.....

for the above named pharmacists who have signed the PGD to work under it.

| Name | Designation | Signature | Date |
|------|-------------|-----------|------|
| | | | |

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

PGD reference HCC202012. Version 1.1a

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The patient group direction is to be read, agreed and signed by each registered pharmacist it applies to. One copy should be given to each participating Pharmacist. The original signed copy should be retained and be easily available within the Community Pharmacy.