

APPROVED PROVIDER LIST FOR THE PROVISION OF VARENICLINE

1. Population Needs

1.1 National/local context and evidence base

All advice and activities will be based on, or contribute to, evidence based research and will be compliant with relevant guidelines, as well as standards for practice as set out in:

National Policy Drivers:

- Smoking Kills - DOH 1998
- Brief interventions and referral for smoking cessation in primary care and other settings - NICE 2006
- Smoking cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach communities – NICE 2008
- How to stop smoking in pregnancy and following childbirth – NICE 2010
- A smoke free future: A comprehensive tobacco control strategy for England – DOH 2010
- Tobacco Control Plan for England – DH 2011
- Smoking cessation in secondary care: acute, maternity and mental health services – NICE 2013
- 2010-2015 government policy: smoking - DOH 201

Local Policy Drivers:

- IW Health and Wellbeing plan
- IW Prevention strategy
- JSNA

2. Scope

2.1 Service description/care pathway

- The supply of Champix® (Varenicline) Tablets 500mcg and 1mg by registered community pharmacists for smoking cessation / management of nicotine withdrawal for adults engaged with the Family Wellbeing Service Isle of Wight. In Community Pharmacy for Isle of Wight Public Health Commissioned Services to clients referred by Public Health Wellbeing Service (Wellbeing advisors) who present with valid identification and information matching that as supplied by the Wellbeing advisor via Pharmoutcomes.
- To record the administration of the supply of Varenicline on the Pharmoutcomes system.
- To liaise with the Wellbeing Service regarding issues arising from the dispensing of the Varenicline.

2.3 Confidentiality

- All patients attending the service will be guaranteed their right to confidentiality is respected and maintained in accordance with IW Council policy
- Informed consent is understood in the terms of a patients ability to understand the choice and consequences, including the nature, purpose and possible risk of any treatment (or non-treatment). In assessing capacity to consent the provider needs to refer to the Department of Health (DOH) Reference Guide to consent for examination or treatment (2001)
- Patients will be treated with dignity and respect taking into account diversity and

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cultural differences.

- Services will be provided to the highest possible clinical quality and accessibility
- Services will be delivered in line with local safeguarding policies and guidelines with joint working arrangements in place to respond to concerns.
- The service will continuously review provision, ensuring that there is emphasis on the needs of the vulnerable and disadvantaged groups and those areas under-provision are identified and addressed.
- The service will have in place arrangements for managing pressures associated with vacancies and staff absence to ensure that service safety, quality and consistency are not compromised, including early communication/warning to commissioners in the event of potential difficulties that may arise in order that the situation can be effectively managed.
- The service will have effective risk management in place.
- There will be clear protocols in place for safe and effective practice and arrangements for clinical governance.
- The service will undertake audits to ensure that services are clinically effective and meet quality criteria and publish results to commissioners.

It is the Wellbeing advisors responsibility to document and maintain records on all patients attending the service, in accordance with locally agreed record keeping policy. Patient notes will also include records on the advice, counselling and treatment received by patients.

Records to be kept by pharmacy

The following will be recorded on PharmOutcomes in the patient records:

- Indication (Smoking cessation)
- Treatment provided (Champix titration pack/ Champix pack)
- Batch number and expiry date
- Duration of treatment (12 weeks)
- Date of supply(No more than 2 courses of Champix allowed)
- Start of treatment and quit date
- Name of the pharmacist assessing the patient and making the supply
- Confirmation of regular attendance of Wellbeing service
Stop Smoking support
- Copies of records and consent forms must be kept for 2 years
- Information must be sent to the GP for entry into the patients records
- Document any allergies and other adverse drug reactions clearly in the patient records and inform GP and Wellbeing Service and any other relevant practitioners/ carers for further reporting and action if needed
- Copies of records and consent forms must be kept for 2 years
- Information must be sent to the GP for entry into the patients records
- Document any allergies and other adverse drug reactions clearly in the patient records and inform GP and other relevant practitioners/ carers for further reporting and action if needed
- Procedure for reporting Adverse Drug Reactions (ADRs)
- All ADRs/ significant events/ near misses occurring in relation to the administration of this medicine under the PGD must be reported in the clinical record and the CCG incident reporting system.
- The GP must be informed and, in a case requiring hospital admission or resulting in serious harm, the incident reported on a yellow card to the Committee on the Safety of Medicines (CSM) - <http://www.bnf.org/bnf/bnf/current/yellow.htm>.

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2.4 Population covered

The service will be available to all smokers referred by the Wellbeing Service only and must be living on the Isle of Wight. The service will be available Monday – Friday 9am -5pm. (Sat and Sun dependant on pharmacy opening hours)

2.5 Any acceptance and exclusion criteria

Clinical condition or situation to which this PGD applies

- NICE: Varenicline is recommended, within its licensed indications, as an option for smokers who have expressed a desire to quit smoking.

It should normally be prescribed only as part of a programme of behavioural support.

Inclusion criteria

Referred following initial consultation with the Isle of Wight Wellbeing Service (WBS) and engaged with their behavioural support programme for 12 weeks.

- Current dependent smokers, who have expressed a desire to stop smoking and have set a quit date.

Exclusion criteria

- Pregnant women, or possible pregnancy
- Breast feeding mothers
- Known hypersensitivity to varenicline
- Known hypersensitivity to any ingredient of the product being supplied
- Patients with epilepsy, conditions that lower the seizure threshold or a predisposition to seizures
- History of unstable cardiovascular disease
- History of psychiatric illness or currently being treated for depression
- Renal impairment – no dose adjustment if estimated creatinine clearance $\geq 30\text{ml/min}$.

Cautions (including any relevant action to be taken)

- If patient is taking any other medications, consult BNF or emc.
- Physiological changes resulting from smoking cessation, with or without treatment with CHAMPIX, may alter the pharmacokinetics or pharmacodynamics of some medicinal products, for which dosage adjustment may be necessary (examples include theophylline, warfarin and insulin).
- As smoking induces CYP1A2, smoking cessation may result in an increase of plasma levels of CYP1A2 substrates.

Arrangements for referral for medical advice

Contact details of services available to be provided to patient, with hours of opening.

Pharmacist to provide written summary of assessment for patient via PharmOutcomes electronic transfer to GP and Wellbeing advisors giving behavioural support, including reason for referral.

Action to be taken if patient excluded

Explain reason for exclusion and refer patient back to Wellbeing Service if support and NRT required.

Refer patient back to Wellbeing Service.

Action to be taken if patient declines treatment

None Necessary.

3. Applicable Service Standards

Training and competency of registered community pharmacies

Requirements of registered pharmacist working under the PGD

Qualifications and professional registration	Pharmacist currently registered with General Pharmaceutical Council (GPhC)
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Initial training & additional requirement	Completion of education in both the legal and professional aspects of PGD administration and the supply of medicines using: <ul style="list-style-type: none">• GPhC codes of Professional Conduct• Legal framework of PGD's• Medicine, Ethics and Practice: Royal Pharmaceutical Society (RPS)• Successful completion of self-assessment of competency form in the use of this medicine for the indications stated The Pharmacist must complete electronic declaration (enrolment) via PharmOutcomes, by clicking on Varenicline PGD tab.
Competency assessment (CPPE Declaration of Competence)	<ul style="list-style-type: none">• College of Pharmacy Postgraduate Education (CPPE) distance learning pack "Learning about stop smoking support" https://www.cppe.ac.uk/programmes/l/smoking-g-01/• Optional - The National Centre for Smoking Cessation and Training (NCSCT) "Stop smoking practitioner training and certification" assessment programme: www.cppe.ac.uk/programmes/l/smoking-e-01/
Ongoing training and competency	<ul style="list-style-type: none">• The Pharmacist is responsible for keeping him/herself aware of any changes to the recommendations for the medicine listed.• It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of their own individual scope of practice.
4. Key Service Outcomes	
<ul style="list-style-type: none">• All 100% of people sent from the wellbeing service to the pharmacy are supplied with provision they have requested.• Ensure referrals are responded to within 3 working days.• Ensure communication channels between wellbeing service and pharmacists	
5. Location of Provider Premises	
Wellbeing workers are transient. Contact information for them can be found on Pharmoutcomes. Pharmacists are at 31 premises Island wide.	
6. Individual Service User Placement	
<u>N/A</u>	
7. Payment Schedule	
Payment will be made monthly, in arrears based on activity. Payment will consist of:	

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- Reimbursement for the specified product at the shown cost plus 5% VAT
- Payment of £10 for the first assessment and supply contact.
- Payment of £4.50 for the 5 following monitoring and supply contacts.

In order for the transaction to be valid, the requisite information **must** be recorded on Pharmoutcomes. Transactions completed that are not recorded on Pharmoutcomes will not be paid.

8. Individual Pharmacy sign up

In order to qualify for payment, pharmacies must complete the 'self-declaration' on Pharmoutcomes confirming that they are providing the service.

The self-declaration form can be found in Pharmoutcomes by following Services > Stop Smoking > pharmacy declaration.

Once this has been completed the pharmacy can be added to the provider list within Pharmoutcomes and be registered for payment.

Without the declaration being completed no payments can be made.