 

**Patient Group Direction**

The supply of

**Varenicline (Champix®) Tablets 500mcg and 1mg**

by registered community pharmacists for

**smoking cessation / management of nicotine withdrawal**

**for adults engaged with the Wellbeing Service Isle** **of Wight**

In Community Pharmacy for Isle of Wight Public Health Commissioned Services

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| 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 most recent and in date final signed version of the PGD should be used. |

**Version number: 1**

**Change history**

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| **Version number** | **Change details** | **Date** |
| 1.0 | First draft | 18 January 2018 |
| 2.0 | Second draft | 15 April 2020 |
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| PGD approval date/ Valid from: | X.4.2020 |
| CCG implementation date: | X.4.2018 |
| Review date: | 1.1.2022 |
| Expiry Date: | 30.4.2022 |

**Champix PGD Accountability Record**

**Verifying the PGDs on behalf of Isle of Wight Council Public Health**

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| **PGD Review Group 2020** | | | |
| **Name** | **Job title and organisation** | **Signature** | **Date** |
| Lead author & pharmacist | Caroline Allen  Deputy Head of Medicines Optimisation |  |  |
| Lauren Stott | Senior Public Health Practitioner |  |  |
| **PGD Authorisation**  ***This PGD has been approved and authorised for use by:*** | | | |
| **CCG Clinical Approval** | | | |
| **Name** | **Authorising Professional** | **Signature** | **Date** |
| **Dr Adam Poole** | Clinical Commissioning Group (CCG) GP Prescribing Lead |  | .2020 |
| **Louise Spenser** | CCG Deputy Director of Nursing and Quality |  | .2020 |
| **Tracy Savage** | CCG Locality Director and Head of Medicines Optimisation and Primary Care |  | 2020 |
| **Verifying the PGDs on behalf of Isle of Wight Council Public Health** | | | |
| **Name** | **Authorising Professional** | **Signature** | **Date** |
| **Simon Bryant** | Director of Public Health Isle of Wight Council |  |  |
| **Provider Organisation (adoption if needed)** | | | |
| **Name** | **Authorising Professional** | **Signature** | **Date** |
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| **Please note:**  **Individuals signing as the ‘manager of the healthcare professionals using the PGD’ have the responsibility to ensure ALL staff working to the PGD legally recognised to do so.**  **Staff should be trained and competent, and their competency should be regularly updated** | | | |

**Training and competency of registered community pharmacists**

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|  | **Requirements of registered pharmacist working under the PGD** |
| Qualifications and professional registration | Pharmacist currently registered with General Pharmaceutical Council (GPhC)  <https://www.pharmacyregulation.org/registers/pharmacist> |
| Initial training | * Completion of education in both the legal and professional aspects of PGD administration and the supply of medicines using:   + GPhC Standards For Pharmacy Professionals   + 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) | * Declaration of Competence CPPE Stop Smoking’ must be undertaken by all pharmacists providing Varenicline (Champix®) under this PGD. * College of Pharmacy Postgraduate Education (CPPE) distance learning:   Mandatory: Stop Smoking: Core and Foundation Learning <https://www.cppe.ac.uk/gateway/smoking> |
| Additional requirements | * Organisational policy on operating under PGD’s |
| Ongoing training and competency | * 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. * The pharmacist is required to complete the required training and competency declaration every time a new contract is signed as this may change slightly in line with current evidence. |

*Retain a copy of each version of the Patient Group Direction for ten years. A copy of this PGD should be given to the CCG, the healthcare professional(s) listed above, their manager(s) and the original is to be retained by the Prescribing Advisor/ Manager.*

**The supply of Varenicline tablets 500 mcg by registered community pharmacists** **for smoking cessation / management of nicotine withdrawal for adults on the Isle of Wight.**

**Clinical condition**

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| **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.   * Adults aged 18 years or over (consider renal function in elderly). * Current dependent smokers, who have expressed a desire to stop smoking and have set a quit date. * A medical history is taken and documented to establish that there are no contraindications for treatment with varenicline (Champix ®) and that any cautions for use are recorded. * Informed consent has been obtained and documented. |
| **Exclusion criteria** | * Client not registered with a GP * Individual under 18 years of age * Smokers already receiving varenicline (Champix ®) prescribed by their GP * Current treatment with nicotine replacement therapy (NRT) or bupropion (Zyban®) * No valid consent * Pregnant women, or possible pregnancy * Breast feeding mothers * Known hypersensitivity to varenicline * Known hypersensitivity to any ingredient of the product being supplied * Patients who have previously had Steven-Johnson syndrome or Erythema Multiforme * Suicidal behaviour and varenicline: Patients should be advised to discontinue treatment and seek prompt medical advice if they develop agitation, depressed mood, or suicidal thoughts. Patients with a history of psychiatric illness should be monitored closely while taking varenicline. * Patients who have experienced serious or worrying side effects from a previous course of varenicline (If serious neuropsychiatric symptoms occur whilst on varenicline treatment, patients should discontinue varenicline immediately and contact a healthcare professional for re-evaluation of treatment) |
| **Cautions (including any relevant action to be taken)** | * Patients with epilepsy, conditions that lower the seizure threshold or a predisposition to seizures * History of cardiovascular disease * History of psychiatric illness (may exacerbate underlying illness including depression); * Renal impairment –dose adjustment if estimated creatinine clearanceless than 30ml/min. * If patient is taking any other medications, consult BNF or emc. * Physiological changes resulting from smoking cessation, with or without treatment with Varenicline, may alter the pharmacokinetics or pharmacodynamics of some medicinal products, for which dosage adjustment may be necessary (examples include theophylline, warfarin and insulin). * As smoking induces CYP1A2, smoking cessation may result in an increase of plasma levels of CYP1A2 substrates. * Any suspected adverse reactions should be reported through the yellow card scheme (e.g. depression). * Patients taking varenicline should be instructed 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 or stroke. * Clients taking theophylline or warfarin. Blood levels of these drugs may increase as a result of stopping smoking and not as a direct drug interaction with varenicline. Blood levels of theophylline and INR for warfarin should be monitored closely. Clients must be advised that they should inform their treatment provider that they are starting varenicline and that they should have their levels re-tested before taking varenicline and regularly whilst taking varenicline * Clients taking insulin should be informed to consider increasing their blood glucose monitoring. This is an effect due to smoking cessation and is not as such an interaction with varenicline. |
| **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  Document action taken. |
| **Action to be taken if patient declines treatment** | Discuss alternative products if suitable and / or refer to Wellbeing Service for further assessment of advice and information. Document action taken. |

**Details of the medicine/ Description of treatment3**

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| **Name, form and strength of medicine**  *Include ▼for* [*black triangle medicines*](http://www.mhra.gov.uk/Safetyinformation/Howwemonitorthesafetyofproducts/Medicines/BlackTriangleproducts/index.htm) | Varenicline (Champix®) tablets 500mcg +1mg |
| **BNF Chapter Category** | 4 Nervous System  8.2 Nicotine dependence |
| **Legal category** | POM |
| ***Indicate any*** [***off-label use***](http://publications.nice.org.uk/patient-group-directions-gpg2/appendix-a-glossary#off-label-use) ***(if relevant)*** | N/A |
| **Dose and frequency** | 500mcg tablet to be taken every day for 3 days,  increased to 500mcg twice a day for 4 days.  Then 1mg tablets twice a day for 11 weeks.  Reduce dose if not tolerated to 500mcg twice a day. |
| **Route/method of administration** | Oral |
| **Total Quantity to be supplied** | 12 week course in 2 weekly instalments:  11 tablets 500mcg and 154 tablets 1mg  or part/all of the 154 tabs maintenance dose as 0.5mg tablets |
| **Maximum treatment period** | Start 1-2 weeks before target stop date (can be extended up to 5 weeks)  **12 week course**  **Repeat ONLY ONCE for relapsed individuals – second referral required from Wellbeing Service** |
| **Adverse effects** | ***For full list of Adverse Drug reactions (ADR’s) see British National Formulary (BNF)/ Summary of Product Characteristics (SmPC)***  **Common**  Taste disturbance, abnormal dreams, appetite changes, dizziness, drowsiness, dry mouth, gastro-intestinal disturbances, headache and sleep disorders |
| **Records to be kept** | The following will be recorded on PharmOutcomes in the patient records:   * Individual’s name, address, date of birth * Indication (Smoking cessation) * Treatment provided (varenicline titration pack/ varenicline pack) * Past and current medical history including medication that is relevant to varenicline including psychiatric history, long term conditions, familial traits. * Allergies relevant to varenicline, see exclusions and cautions * Individual’s consent * GP contact details * Name of medication, batch number, expiry date * Dose * Duration of treatment (12 weeks) * Date of supply (No more than 2 courses of varenicline 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 * Details of any adverse drug reactions and actions taken including documentation in the patient’s medical record. * Give individual a copy of the manufacturer’s Patient Information Leaflet and advise them accordingly with particular reference to the potential to cause drowsiness * Signposting / referral arrangements * Inform client’s GP of varenicline after obtaining consent from client   The pharmacist must keep a record of the consultation for at least 8 years for an adult.  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. |

***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 to publichealth@iow.gov.uk*

*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) -* [*https://yellowcard.mhra.gov.uk*](https://yellowcard.mhra.gov.uk)

**Client information**

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| **Written/ verbal information to be given to patient or carer** | **Highlight the patient information leaflet included in the box, including:**   * Advise patient to take at regular intervals * Advise the patient that this is a 12-week course to support abstinence after the quit date * Tablets should be swallowed whole with a full glass of water, with or without food * Advise patient that if they experience any of the common side effects they may reduce the dose * Advise patient to discontinue treatment and seek prompt medical advice if they experience:   + Agitation, depressed mood or suicidal thoughts   + Rash or skin reaction. * Provide advice on ways to support smoking cessation * Give the patient any available literature available on smoking cessation * Advise patient of risk of relapse, irritability, depression, and insomnia on discontinuation; consider dose tapering (1mg daily) during the last week of the course * Advise patient full course of 12 weeks will not be prescribed without weekly attendance of Wellbeing Service stop smoking support. * Champix PGD leaflet should be given to the patient (<https://www.medicines.org.uk/emc/medicine/19042>). * Driving and skilled tasks: Manufacturer advises patients and carers should be cautioned on the effects on driving and performance of skilled tasks—increased risk of dizziness, somnolence, and transient loss of consciousness. |
| **Follow-up advice to be given to patient or carer** | * Weekly attendance of Wellbeing service stop smoking support is required * Advise to see Wellbeing Service if not successful * Follow up with pharmacist every 2 weeks for ongoing supply of varenicline, with discussion of compliance and adverse effects. |

**Appendix 1**

**Key references**

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| 1. BNF March 2020 <https://bnf.nice.org.uk/drug/varenicline.html> 2. EMC SmPC <http://www.medicines.org.uk/emc/medicine/19045> & PIL <http://www.medicines.org.uk/emc/medicine/19042> 3. CPPE Gateway: <https://www.cppe.ac.uk/gateway/smoking> 4. NICE Varenicline for smoking cessation (July 2007, reviewed 2011) TA 123 <https://www.nice.org.uk/guidance/ta123> 5. Public Health England /NCSCT 2014 guidance <http://www.ncsct.co.uk/usr/pub/LSSS_service_delivery_guidance.pdf> |

**Appendix 2:**

**PGD Sign-Off Sheet 2020-22**

Health professionals’ agreement to practise

To be signed by individual health professionals agreeing to practice under the PGD.

I have read and understood the patient group direction, completed the prerequisite training and agree to supply and/or administer this medicine only in accordance with this PGD.

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| **Pharmacist Name** | **GPhC Number** | **Date** | **Signature** |
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*A copy of this PGD should be given to the Council, the healthcare professional(s) listed above, and the original is to be retained by the Provider Manager.*

**Appendix 3**

**Treatment Plan**

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| **Consultations** | **Treatment plan** |
| **Clinical Assessment:**   * Day One | * Patient referred to pharmacy by **WBS** for clinical assessment and initial supply. Referral confirmed via Pharmoutcomes. Patient should have a quit date set and agreed with **WBS**. * Supply 14 day starter pack (11 x 500 mcg tabs with 14 X 1mg tablets) |
| **Repeat Supplies:**   * Day Fourteen * Day Twenty Eight * Day Forty Two * Day Fifty Six * Day Seventy | * Patient referred back by **WBS** for further supplies. Discuss compliance and check for adverse effects. * Supply 28 x 1mg varenicline tablets if no issues or 28 x 0.5mg varenicline tablets if reduced dose needed. |

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**Appendix 4**

**Pharmacist Payment**

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|  | Drug Tariff (Mar 2020) | PharmOutcomes |
| Pharmacist Initial Clinical Consultation | £27.30 | £10.00 |
| Repeat Dispensing’s (x5) | £27.30 x 5 | £4.50 x 5 |
| **Total** | **£163.80** | **£32.50** |

**Appendix 5**

**PharmOutcomes**

The system will factor invoices:

* £10.00 where “Period of supply” = Pharmacist patient consultation and initial supply (VAT Exempt) (Initial consultation)
* Where ‘*Product Supplied*’ *=* The value of ‘*Product Supplied (DM&D)*’ x ‘*Quantity Supplied*’ *in pence* plus VAT at Low rate (Product Reimbursement)
* Where ‘*Product Supplied*’ *=* The value of ‘*Product Supplied (DM&D)*’ x ‘*Quantity Supplied*’ *in pence* plus VAT at Low rate (Product Reimbursement)

£4.50 where ”Period of Supply” not = Pharmacist patient consultation and Initial Supply (VAT Exempt) (Subsequent Consultation)

The system will allow data to be claimed for at the time of issue. Payment by Commissioner will be monthly.

**Appendix 6**

**IOW Wellbeing Service (WBS)**

Initial assessment of patient suitability for varenicline by WBS and then referred to Pharmacy for clinical assessment and approval

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**Community Pharmacy**

Clinical consultation with pharmacist to assess the patient for suitability for varenicline.

**If patient suitable -** pharmacist supplies 2 week titration pack

**If patient unsuitable -** pharmacist informs patient to contact **WBS** for exploration of other options

**Pharmacist completes Pharmoutcomes**

* Feedback to GP that the patient has been issued with varenicline for their clinical records via PharmOutcomes automated notification.
* Pharmacy payment

**WBS authorisation through Pharmoutcomes**

Pharmacist to supply next 2-weeks of medication until all 6 supplies are made

**Repeat ONLY ONCE for relapsed individuals.**

**Second referral required from Wellbeing Service.**