

Supply of Varenicline within Community Pharmacies Service Specification

1. Population Needs

1.1 National/local context and evidence base

- 1.1.1 Smoking remains the leading cause of preventable death and disease nationally and locally and is one of the most significant factors that affect health inequalities and ill health, particularly cancer, coronary heart disease and respiratory disease. Reducing smoking prevalence therefore remains a key public health priority and a national focus.
- 1.1.2 The national tobacco control plan (2017), Towards a Smokefree Generation: Tobacco Control Plan for England has set out the following objectives to be achieved by the end of 2022
- reduce the number of 15year olds who regularly smoke from 8% to 3% or less
 - reduce smoking among adults in England from 15.5% to 12% or less
 - reduce the inequality gap in smoking prevalence, between those in routine and manual occupations and the general population
 - reduce the prevalence of smoking in pregnancy from 10.5% to 6% or less
- 1.1.3 NICE guidance clearly identifies a number of effective stop smoking interventions for everyone involved in, or responsible for stop smoking services, including brief intervention, individual behavioural counselling, group behaviour therapy, pharmacotherapy, self-help materials, telephone counselling and quit lines.
- 1.1.4 Providers must work with the Council to deliver Services in line with all National Standards.

1.2 Evidence Base

- 1.2.1 Stop Smoking Services that are underpinned by guidance from the National Institute for Health and Care Excellence (NICE) are highly effective in both cost and clinical terms. Smokers are four times more likely to quit using stop smoking behavioural support and medication than quitting unaided or using nicotine replacement therapy over the counter (PHE 2014)
- 1.2.2 The evidence base and national standards for service delivery are set out below:
- National Institute for Health and Care Excellence (NICE) TA123 Smoking cessation – varenicline (2007)
 - National Institute for Health and Care Excellence (NICE) Stop smoking interventions and services NICE guideline [NG92] (March 2018)
 - National Institute for Health and Care Excellence (NICE) Public Health Guidance 10: Smoking Cessation Services (February 2008)
 - National Institute for Health and Care Excellence (NICE) QS43 Smoking cessation: supporting people to stop smoking (2013)
 - National Centre for Smoking Cessation and Training (NCSCT) Local Stop Smoking Services: Service and Delivery Guidance (2014)
 - HM Government Towards a Smokefree Generation: A Tobacco Control Plan for England (2017)

2. Scope

2.1 Service Model

- 2.1.1 This Service Specification is designed only to cover the supply of Varenicline via the Living Well Smokefree Community Pharmacy Varenicline PGD Scheme.
- 2.1.2 Varenicline is prescribed only as a component of smoking cessation support programme. Treatment should be limited to 12 weeks and prescribing intervals should be short and dependent upon continual attendance at treatment clinics.
- 2.1.3 Only one treatment episode of Varenicline (up to 12 weeks) can be offered in a six month period and the Service User must remain abstinent from smoking after their quit date (between day 8 and 14). Payment maybe withheld by the Council if this is not adhered to. Service Users who already have previously quit using Varenicline in the same year and relapsed cannot be offered Varenicline treatment again until six months have passed since the last treatment started.

2.2 Aims and Objectives of the Service

- 2.2.1 The purpose of this Service Specification is to enable safe and appropriate access to Varenicline as an aid to stop smoking and ensuring Service Users who are smokers have an accessible treatment service to help them to stop smoking.
- 2.2.2 As Varenicline is licensed as an option for smokers who have expressed a desire to quit smoking, the aim of this Service is enable the supply of Varenicline therapy from community pharmacy via a Patient Group Direction, as part of the commissioned stop smoking service.
- 2.2.3 This pharmacy-based service will help to increase choice and improve access to stop smoking medication by providing the population with a greater number of places to access Varenicline pharmacotherapy with additional support and advice for patients. It will contribute to local public health and tobacco control strategies, which have a commitment to reduce smoking and contribute to the targets measured by the number of smokers who stop.
- NICE has made recommendations for the use of Varenicline for smoking cessation.
- 2.2.4 Through ease of access to appropriate stop smoking treatments this Service will contribute to reduction in harm from tobacco and to the achievement of local and national targets including:
- A reduction in smoking prevalence across North Yorkshire
 - Reduce smoking related illness & deaths by helping people give up smoking
 - To provide smoking cessation services to 5% of local smokers each year
 - To help reduce smoking prevalence to 5% in North Yorkshire by 2025
- 2.2.5 The PGD scheme is designed to significantly improve service delivery from pharmacies by enabling them to supply Varenicline treatment without the need to have a NHS prescription in place first. It enables Service Users to have timely access to Varenicline treatment following a recommendation made by the accredited stop smoking advisor that is supporting them.
- 2.2.6 To increase the support and advice to Service Users that wish to cease smoking.
- 2.2.7 To increase the numbers of quitters in more deprived areas where there are high numbers of people living in poverty, high rates of unemployment and inadequate housing.
- 2.2.8 To raise people's awareness of the risks of smoking and the support available to help smokers to quit.

- 2.2.9 To develop and enhance the skills of the Service staff to improve the public health provision within the population of North Yorkshire.
- 2.2.10 To ensure Service Users who are smokers have access to a treatment service to help them to quit.
- 2.2.11 To contribute to local public health and tobacco control strategies, which have a commitment to reduce smoking, particularly in vulnerable patient groups.
- 2.2.12 To contribute to the Council's target measured by the number of smokers who stop at four weeks.

2.3 Service Description/Care Pathway

- 2.3.1 The Service will be provided by trained and accredited pharmacy staff (pharmacists and stop smoking advisors) based in accredited community pharmacies located within North Yorkshire and trained Living Well Smokefree specialist smoking cessation advisors. Members of the general public who wish to stop smoking will access the service by referral/self-referral to the Living Well Smokefree Service or to a Council accredited community pharmacy.
- 2.3.2 The Living Well Smokefree specialist stop smoking advisor (or in-house pharmacy stop smoking advisor from pharmacies providing a complete smoking cessation service) will assess the Service User using standard monitoring and assessment criteria (NCSCCT Standards), provide initial stop smoking advice/support and where Varenicline has been determined as the most suitable pharmacotherapy intervention, complete a standard "Varenicline screening questionnaire for advisors (See Appendix 1). The advisor will then issue the Service User a completed "*Letter of recommendation to supply Varenicline*" or equivalent and a copy of the completed Varenicline screening-questionnaire to take to an accredited pharmacy/pharmacist (See Appendix 2).
- 2.3.3 The accredited pharmacist will then check the Service User is clinically suitable to receive Varenicline treatment using the criteria set out in the PGD before supplying a two week starter pack of Varenicline tablets. The pharmacist will inform the Service User's GP within 24 hours of supply and request GP to contact the pharmacy (within 72hrs from time of supply) if they feel Varenicline supply is not suitable.
- 2.3.4 Further 14 day supplies of Varenicline will be made in fortnightly installments, in line with the Varenicline PGD and only following the receipt of a letter issued by the advisor (to the Service User or directly to the pharmacy) recommending follow up Varenicline supplies and confirming that the Service User is in receipt of regular weekly support and noting any side effects. (See Appendix 4 for an example letter). N.B. Behavioral support must be provided weekly for at least the first 4 weeks of treatment, after which, it may be reduced to fortnightly but only if deemed clinically appropriate by the advisor.
- 2.3.5 Subsequent supplies will be made in this way. Varenicline can be used for up to 12 weeks. Changes may be made during treatment by the pharmacist if clinically appropriate in line with the PGD. The pharmacy will record the required minimum data set onto the Varenicline PGD PharmOutcomes template. Service Users will be required to access regular (weekly or bi-weekly) behavioural support from their stop smoking advisor for the duration of their quit attempt.

2.4 Entry into Service (referral routes)

- 2.4.1 The only entry mechanism is by referral with a "letter of recommendation to supply Varenicline" from a trained and accredited stop smoking adviser. (See Appendix 2 for an example letter).

2.5 Service Delivery Particulars

- 2.5.1 Accredited pharmacies will act as a dispensing point for Varenicline supply under PGD within this Service.
- 2.5.2 Being a dispensing point means being available for advice and dispensing of Varenicline. Pharmacies will be available for dispensing Varenicline throughout their contracted opening times.
- 2.5.3 Varenicline can only be dispensed at an accredited pharmacy under the Council's Varenicline PGD via this Service Specification to Service Users presenting the pharmacist a letter of recommendation to supply Varenicline (or a follow up to supply letter) completed by an accredited stop smoking adviser (See Appendix 2 and Appendix 4 respectively).
- 2.5.4 Only two week's supply of Varenicline should be supplied at a time in line with the current Council Varenicline PGD.
- 2.5.5 The area of the pharmacy used for provision of this Service must provide a sufficient level of privacy and safety. The pharmacy should have, or ultimately be working toward having a private consultation area which meets the regulatory requirements for advanced services (as set out in the drug tariff and GPhC standards for registered pharmacies) as a minimum.
- 2.5.6 The Provider must ensure that confidentiality for all Service Users is assured.
- 2.5.7 To ensure continuity of care the scheme will require the Service Users to have all their Varenicline supply (for their current quit attempt) to be dispensed at the same pharmacy.
- 2.5.8 Following a pre-quit assessment if it is determined that Varenicline is the pharmacotherapy intervention of choice, then the Service User's stop smoking advisor must complete a "Varenicline screening questionnaire for advisors" to help assess Varenicline suitability and to provide additional information to the pharmacist before referring the Service User to an accredited pharmacy/pharmacist (See Appendix1).
- 2.5.9 To refer a Service User to an accredited pharmacy/pharmacist, the advisor must complete and issue the Service User a "Letter of recommendation to supply Varenicline" (See Appendix 2) and a copy of the completed "Varenicline screening questionnaire for advisors" to take to the pharmacist.
- 2.5.10 The Smoking Advisor who has written the letter of recommendation should be informed of any delays in starting treatment.
- 2.5.11 After reviewing the advisor's letter and questionnaire the nominated pharmacist must check the Service User is clinically suitable to receive Varenicline treatment using the criteria set out in the PGD, before supplying a two week starter pack of Varenicline tablets. The pharmacist should complete the "*PGD Assessment Pro forma*" to assist in this process (see Appendix 3).
- 2.5.12 If Varenicline is clinically suitable the Service User should set a quit date 7 to 14 days after treatment initiation.
- 2.5.13 Service Users excluded from the PGD should be referred back to their stop smoking adviser with an explanation that the Service User is unsuitable for Varenicline.
- 2.5.14 The Pharmacist will dispense, label and supply the initial two week supply Varenicline starter pack (Supply one) as per PGD recommendation and complete the relevant records for this supply, including the PharmOutcomes template and Form 1- "Record of Supply of Varenicline," (See Appendix 7).

- 2.5.15 The Service User must complete the declaration section on the back of the “Record of Supply of Varenicline” for each two week supply of Varenicline made (Appendix 7). For Service Users that are not eligible for exemption from NHS prescription charges, this will mean the Provider will collect a fee equivalent to the standard NHS prescription charge for each Varenicline supply. This fee will be deducted from the total reimbursement payment made to the Provider.
- 2.5.16 The Service User must be seen weekly by their Stop Smoking Adviser for up to 12 weeks. After 4 weeks the frequency of behavioural support may be reduced to every two weeks, but only if this is deemed suitable by the Adviser.
- 2.5.17 The Service User’s GP will be notified by the Pharmacist of the first supply of Varenicline via the PharmOutcomes template or by using a standard physical letter, to allow the GP to intervene if necessary.
- 2.5.18 The Pharmacist will inform the Service User’s GP, using either the electronic letter template process available within the PharmOutcomes system or using an equivalent standard letter within 24 hours of supply and request the GP to contact the Pharmacy (within 72hrs from time of supply) if they feel Varenicline supply is not suitable. (See Appendix 6 for an example letter)
- 2.5.19 At two weeks, Pharmacists should confirm that Service User has quit and that the GP has not objected to the Service User receiving Varenicline and that the Service User is receiving behavioural support sessions on a regular basis and noting any side effects.
- 2.5.20 All further supplies will be made at 2 weekly intervals only after confirmation is received from the Stop Smoking Adviser that the Service User is continuing to attend behavioural support sessions on a regular basis and that they have checked if the Service User is experiencing any adverse effects (noting any adverse effects being experienced) and that the Service User should continue on Varenicline.
- 2.5.21 Notification confirming this to the supplying Pharmacist will be made by the Stop Smoking Adviser by completing the “Letter of recommendation for follow up Varenicline supply” or equivalent (see Appendix 4 for example letter). The correct reference/ Service User ID must be used in all correspondence to correlate the data at all times.
- 2.5.22 If the Service User has suffered adverse side effects, then the Service User should be counselled and advised to discuss these with the supplying Pharmacist. The Service User’s Stop Smoking Adviser should be informed of any changes to treatment.
- 2.5.23 Service Users who develop any serious adverse effects, including any signs of agitation, depressed mood, suicidal thoughts or other serious mood changes must be referred to their GP for prompt medical advice. The Pharmacist should contact the Service User’s GP surgery and try to arrange an appointment for the Service User to see the GP.
- 2.5.24 The Pharmacist can refuse to dispense Varenicline if the Service User has failed to maintain fortnightly collections or has failed to attend two consecutive behavioral support sessions or has not taken Varenicline for more than 3 days. If no contact is made for two consecutive weeks the Pharmacist will cease dispensing and contact the relevant Stop Smoking Adviser to confirm this.

2.5.25 The final choice is at the discretion of the Pharmacist. The Pharmacist can use their own discretion to refuse the dispensing Varenicline if in their own clinical judgement, it is not deemed suitable to dispense. Should a refused person wish to challenge the decision to refuse, the Provider is to refer that person to their Stop Smoking Advisor for further advice.

3.5.26 All supplies of Varenicline must be recorded on the Service User's medication record (PMR) held at the pharmacy. All Varenicline products supplied via the Varenicline PGD scheme must be labelled and dispensed in accordance with the requirements of the Medicines, Ethics and Practice Guidance, as published by The General Pharmaceutical Council UK.

2.5.27 The Pharmacist in charge at the point of dispensing is the health professional responsible for the dispensing and selection of the Varenicline product for the Service User.

2.5.28 The Pharmacist must:

- Only supply Varenicline products as defined within the Council's PGD
- Not offer pharmacological treatments that have not been approved for use by the Council's Public Health Team
- Not offer Varenicline outside its product license
- Not offer Varenicline when it is clinically inappropriate for the Service User.
- Complete a Yellow Card if an adverse reaction is reported by a Service User (<http://yellowcard.mhra.gov.uk>)

2.5.29 The Provider must have a Standard Operating Procedure that covers the advice and dispensing of Varenicline via PGD.

2.5.30 Varenicline will be provided by the Provider and claimed for via the PGD PharmOutcomes template.

2.5.31 Stop smoking material issued to raise the health promotion messages of smoking cessation support should be clearly displayed.

3. Data Collection

- 3.1 All Provider's providing this Service will need to complete and return the required data to the local authority on a monthly basis, using the Service modules on PharmOutcomes. Support with inputting data onto PharmOutcomes is available via the PharmOutcomes template instruction videos.
- 3.2 All claims are processed via PharmOutcomes. All fields that are presented within the PharmOutcomes Varenicline via PGD template must be complete and accurate.
- 3.3 All activity details must be recorded on PharmOutcomes as soon as possible, and in any event within 7 days after delivery of the intervention to ensure accuracy of information and enable prompt payment. The system will not accept attempts to log activity more than 1 month after the date of delivery of that intervention
- 3.4 The Council will generate the monthly claim report from the system for all Providers and send the report to the Council's Finance Team for payment. There will be no requirement for Providers to send invoices.
- 3.5 Providers must store all relevant Varenicline associated paperwork presented for a period of two years at the dispensing pharmacy in accordance with legislative data handling requirements and audit purposes. After two years relevant Varenicline associated paperwork must be safely destroyed in accordance with the Data Protection Act.

4. Staff and Training Requirements

- 4.1 The Service must be provided by staff employed by the Provider.
- 4.2 The Provider has a duty to ensure that Pharmacists and staff involved in the provision of the Service have relevant knowledge and competence and are appropriately trained in the operation of the Service. All staff, including locums, should be aware of and act in accordance with any relevant local protocols that may be in operation including NICE guidance and local drugs formularies, such as the North Yorkshire Smoking Cessation Formulary (See Appendix 3).
- 4.3 Pharmacy based Stop Smoking Advisors must be trained and have NCSCT certification. Further information is available at the NCSCT website: www.ncsct.co.uk. This online training programme can be accessed through CPPE. (NB. This only applies to Providers that are commissioned to deliver a complete in house Smoking Cessation service and have their own Stop Smoking Advisors. It is not a requirement where the Provider is only acting as a dispensing point for Varenicline via PGD).
- 4.4 All staff involved in the provision of the Service should have up to date knowledge on stop smoking support and smoking cessation products including Varenicline.

5. Requirements for Qualification as Providers

- 5.1 To have a qualified Pharmacist with current Pharmacist Declaration of Competence (DOC) for pharmacy services – Stop Smoking Intervention Service and Pharmacist supply of prescription-only medicines via a patient group direction (See Appendix 9 and following link: <https://www.cppe.ac.uk/services/docs/commissioners/commissioner%20-%20stop%20smoking.pdf>). Pharmacists should register their DOC on the CPPE website. The Provider must inform the commissioner when this DOC has been completed and when subsequent re-accreditation has been completed. This should be done by enabling the CPPE viewer facility via the *Profile* section of the *My CPPE* page to allow access by the Commissioner.
- 5.2 To have approved premises in-line with Standards for registered pharmacies (see Appendix 10 and the following link for reference document: (https://www.pharmacyregulation.org/sites/default/files/document/standards_for_registered_pharmacies_june_2018_0.pdf)
- 5.3 Providers that are providing a complete in-house Smoking Cessation Service and have their own Stop Smoking Advisors will require their Stop Smoking Advisors to have a current DOC for pharmacy services – Stop Smoking Intervention Service (See link for reference document: <https://www.cppe.ac.uk/services/docs/commissioners/commissioner%20-%20stop%20smoking.pdf>)
- 5.4 To be authorised by the Council to supply Varenicline under the PGD
- 5.5 The Service is to be offered during opening times of the Pharmacy
- 5.6 To attend a one off Varenicline PGD training event that will cover the local PGD and its requirements, the service pathway, PharmOutcomes, payments, safeguarding and other aspects of service delivery.
- 5.7 For those who have not delivered this Service before, a six months grace period in attending the Varenicline PGD training event is permitted, so long as provider staff have registered their DOC on PharmOutcomes. For Providers that have previously attended a face to face Varenicline PGD training event in the past 12 months a 12 month grace period will be permitted before needing to attend a training event, so long as the relevant staff have registered their DOC on PharmOutcomes.
- 5.8 Pharmacists employed by the Provider will attend a further training event if the Living Well Smokefree Service or the commissioner feel this would be useful to refresh knowledge.

6. Monitoring and Review

- 6.1 The Service provided in Pharmacies is monitored by the return of Varenicline data via PharmOutcomes
- 6.2 The Provider may be requested to participate in an end of year service review as defined by Public Health.
- 6.3 The Council reserves the right to audit Smoking Cessation Service Varenicline associated documentation held at the Pharmacy against monthly claims made by the Provider. This includes requests for supporting information.
- 6.4 Providers may be subjected to a 'mystery shopper' exercise to ensure compliance with the Service Specification and to ensure service quality.
- 6.5 The Provider will report to the commissioner within 24 hours any complaints relating to service provision within this Specification and/or untoward incidents, e.g. involving Service Users, carers, allergic reaction to medication, violence and aggression towards staff, etc.
- 6.6 The Provider notifies the commissioners immediately if there is likely to be a disruption in the availability of the Service – e.g. trained Pharmacist leaves or goes on long term sickness absence.

7. Payment

- 7.1 Providers that are commissioned to supply Varenicline under a Patient Group Direction to support Smoking Cessation Service will be paid at the following rates:

Activity	Fee
- PGD initial consultation and assessment with first two week supply of Varenicline (starter pack) - Issue letter to GP	£10.00
First review and 2 nd two week supply	£4 (incl. dispensing fee)
Review and 3 rd two week supply	£4 (incl. dispensing fee)
Review and 4 th two week supply	£4 (incl. dispensing fee)
Review and 5 th two week supply	£4 (incl. dispensing fee)
Review and 6 th two week supply	£4 (incl. dispensing fee)
Re-impbursement for Varenicline product costs	Initial re-impbursement will be based on the July 2019 Drug Tariff product costs + 5% VAT. (These prices will be reviewed at least every 6 months). NB. Where PharmOutcomes or other future electronic payment system is used that enables the current Drug Tariff prices to be used automatically then these prices will be used to calculate product cost re-impbursement.

- 7.2 In order for PharmOutcomes to correctly support the payments for dispensing Varenicline, completion of all requested fields and timely submission via PharmOutcomes is essential. As described in section 3.2 this must be within 14 days after delivery of the intervention to ensure accuracy of information and enable prompt payment. The system will not accept attempts to log activity more than 1 months after the date of delivery of that intervention.
- 7.3 In the event of over claims being made, the Council has the right to reclaim all monies.

7.4 No payment will be made retrospectively for any part of this Service conducted prior to its commencement date (August 2019).

8. Acceptance and Exclusion Criteria

8.1 The Service is for all people that live or work in the geographical region of North Yorkshire and are being supported by the Living Well Smokefree Service.

8.2 The Service is only available through community pharmacies in North Yorkshire NYCC Living Well Smoke Free Service.

8.3 It is only currently available to Service Users who are receiving behavioural support from the Living Well Smokefree Specialist Service or from a Living Well Smoke Free community pharmacy in-house Stop Smoking Advisor.

8.4 The Service is to be provided within the locality of North Yorkshire, within the full opening hours of the community pharmacy contract.

9. Interdependence with other Services

9.1 Living Well Smoke Free Varenicline supply via PGD scheme is interdependent with accredited community pharmacies.

9.2 The Service User GP, Pharmacists and Stop Smoking Advisors.

9.3 The Provider is expected to work closely with the Council's Public Health Team to ensure that all claims are processed appropriately.

10. Accessibility of Service

10.1 The Provider will comply with the Equality Act 2010 in the provision of this Service.