

SERVICE SPECIFICATION

Service Specification No.	1.0
Service	Supply of Varenicline Tablets 500mcg and 1mg and Cytisinicline (cytisine) 1.5mg tablets by registered community pharmacists and technicians for smoking cessation for adults engaged with the Portsmouth Wellbeing Service and Pharmacy Smoking Cessation Service
Commissioner Lead	Gareth Spooner - Public Health development manager
Provider Lead	Portsmouth city council and Portsmouth Pharmacies
Period	May 2026
Date of Review	May 2028

1. Background

1.1. National and local context

Smoking is the leading cause of ill health and premature mortality in the UK. Smoking is a major risk factor for many diseases, such as lung cancer, chronic obstructive pulmonary disease (COPD) and heart disease. It is also associated with cancers in other organs, including lip, mouth, throat, bladder, kidney, stomach, liver and cervix.

In 2023, according to the national Annual Population Survey (APS) around 10.1% of Portsmouth adults (aged 18 years and over) were current smokers. This is similar to the estimate for England (11.6%) and the South East region (10.6%).

In 2022/23, the percentage of Portsmouth women smoking at time of delivery (SATOD) was 12.0%. This is significantly higher than England (8.8%) and the South East region (8.1%).

The smoking rates for other areas see a much higher prevalence compared to the adult population in Portsmouth, adults in routine and manual occupations currently stands at 21% (v 22.5% for England) and adults with long term mental health conditions is 22.5% (v 25.1% for England).

1.2. Varenicline and Cytisinicline

Varenicline and Cytisinicline are an effective drug treatment to aid smoking cessation.

Varenicline and Cytisinicline are a licensed Prescription Only Medicine (POM) as defined by the Medicines Act 1968 and Prescription Only Medicines (Human Use) Order 1997.

Varenicline and Cytisinicline is subject to standard monitoring arrangements for adverse events via the Yellow Card Scheme.

This specification is for the provision of Varenicline **and** Cytisinicline within a community pharmacy setting only.

2. Purpose

This specification sets out a model for the supply of Varenicline and Cytisinicline by registered community pharmacists and technicians, in accordance with the approved Patient Group Directions (PGDs), for smoking cessation for adults engaged with the Portsmouth Wellbeing Service and Pharmacy Smoking Cessation Service.

2.1. Aims and Objectives

The aim of the service is to contribute towards providing an effective and safe Stop Smoking Service that contributes to the reduction in the prevalence of tobacco use and its associated harmful health impact within Portsmouth.

The objectives of the service are:

1. To provide access to Varenicline and Cytisinicline to service users engaged with the Portsmouth Wellbeing Service and pharmacy smoking cessation service at a community pharmacy of their choice.
2. To contribute to maximising the number of smokers in Portsmouth quitting smoking for life.
3. To contribute to reducing the socio-economic gap in smoking prevalence by targeting services in communities of highest smoking prevalence and the greatest number of smokers.

3. Service provision

3.1. Location(s) of Service Delivery: Locally commissioned pharmacies.

3.2. Population covered: Portsmouth residents (PO1-PO6) who smoke that are aged 18 and over who are engaged with the Portsmouth Wellbeing Service and pharmacy smoking cessation service.

Wellbeing Service

- 3.3. The Wellbeing Worker will assess the client's motivation to quit and provide ongoing one to one motivational support throughout the quit attempt. If the client expresses a preference for Varenicline or Cytisinicline the Wellbeing Worker conduct an initial assessment for suitability and refer to the exclusion list provided in appendix 3. If there are no contra-indications, refer the client to a participating pharmacy via an e-voucher on PharmOutcomes.
- 3.4. The Wellbeing Worker will provide suitable clients with the current list of participating pharmacies and the client must confirm to the Wellbeing Worker which pharmacy they intend to use.
- 3.5. The Wellbeing Worker will explain to the client that it will be the Pharmacist's decision whether or not to supply their chosen stop smoking medication.
- 3.6. The Wellbeing Worker will advise the client to access the stop smoking medication through one pharmacy to ensure continuity of care and liaison between the Wellbeing Worker and the Service Provider. The pharmacy will provide the full course of treatment at agreed intervals together with associated monitoring.
- 3.7. If the Wellbeing Worker identifies any cautions they may not proceed with a request for Varenicline or Cytisinicline for the client but may offer another form of pharmacotherapy.

Pharmacy Smoking Cessation Service

- 3.8. The pharmacy worker will assess the client's motivation to quit and provide ongoing one to one motivational support throughout the quit attempt. If the client expresses a preference for Varenicline or Cytisinicline the pharmacy worker will conduct an initial assessment for suitability and refer to the exclusion list provided in appendix 3.
- 3.9. The pharmacy worker will explain to the client that it will be the Pharmacist's decision whether to supply their chosen stop smoking medication.
- 3.10. The pharmacy worker will advise the client to access the stop smoking medication through their pharmacy to ensure continuity of care.
- 3.11. The pharmacy will provide the full course of treatment at agreed intervals together with associated monitoring.
- 3.12. If the pharmacy worker identifies any cautions they may not proceed with a request for Varenicline or Cytisinicline for the client but may offer another form of pharmacotherapy.

The Service Provider

- 3.13. The Service will be available throughout the pharmacy's opening hours (both core and supplementary). The Service Provider will maintain an acceptable level of staffing at all times, and will provide suitably accredited, skilled, trained and experienced staff to provide the Service.
- 3.14. The pharmacy will supply Varenicline and Cytisinicline, in accordance with the relevant locally agreed PGD, to clients referred by the Portsmouth Wellbeing Service who present with valid identification and information matching the details supplied by the Wellbeing Practitioner via the e-voucher system on PharmOutcomes.
- 3.15. The pharmacy record the administration of the supply of Varenicline or Cytisinicline on the PharmOutcomes system.
- 3.16. If the outcome of the initial assessment is to not supply Varenicline or Cytisinicline the pharmacy must inform the Portsmouth Wellbeing Service so that an alternative treatment may be offered.
- 3.17. The pharmacy must liaise with the Portsmouth Wellbeing Service regarding any issues arising from the supply of the Varenicline or Cytisinicline.
- 3.18. The pharmacy will inform the client's GP that the client has been issued with Varenicline or Cytisinicline for their clinical records. (Please note this is an automated process on the smoking cessation PGDs service).
- 3.19. The pharmacy must ensure that all pharmacists and technicians involved in the provision of the service operate within the current Patient Group Directions for Varenicline and Cytisinicline.
- 3.20. If Varenicline or Cytisinicline is withdrawn at any stage, the pharmacy must inform the Portsmouth Wellbeing Service so that an alternative treatment may be offered.
- 3.21. The pharmacy only will provide the full course of treatment and not refer the client on to another Service Provider except in unavoidable circumstances e.g. sickness.

- 3.22. The pharmacist can restart a patient on Varenicline within a six month period following a lapse if deemed appropriate. A break of 2–3 months is recommended before starting a new 25-day course of Cytisinicline.
- 3.23. The pharmacist can extend treatment beyond 12 weeks, for example a further 2 weeks, if a referral is made from the Portsmouth Wellbeing Service via PharmOutcomes.
- 3.24. Details of the supply process for Varenicline and Cytisinicline is shown in Appendix 1 for the Wellbeing Service and Appendix 2 for Pharmacy smoking cessation programme.

4. National and local guidance

The Service Provider shall deliver the Service in line with the NHS (Pharmaceutical Services) Regulations 2005 and any other relevant professional standards.

- 4.1. The Service Provider shall take account of any NICE guidelines that are relevant to the Service.
- 4.2. The Service Provider will deliver the Services in accordance with best practice in health care and shall comply in all respect with the standards and recommendations contained in:
 - I. National Service Frameworks and National Strategies
 - II. National Patient Safety Agency alerts and guidance
 - III. Human Medicines Regulations 2012
 - IV. and such other quality standards agreed in writing between the Service Provider and the Council.
- 4.3. The Service Provider will at all times comply with the most recent guidance on medicines from the Medicines and Healthcare products Regulatory Agency (MHRA).

5. Service Standards

- 5.1. **Eligibility to provide the service:** A Pharmacy may be accepted for the provision of this service if it has a partner, employee or sub-contractor who has the necessary skills and experience to carry out the contracted service.

The pharmacy contractor has a duty to ensure pharmacists and technicians involved in the provision of the service:

- have relevant knowledge and are appropriately trained in the operation of the service and all records of assessment must be retained by the pharmacy contractor, together with the signed Varenicline and Cytisinicline PGD
- all pharmacists and technicians must comply with the competency assessment as stated within the locally agreed PGD
- Declaration of Competence CPPE Stop Smoking must be undertaken by all pharmacists providing Varenicline and Cytisinicline

All registered pharmacists and technicians undertaking this service:

- Sign the approved PGD for the supply of Varenicline and Cytisinicline and agree to work in accordance with the PGDs
- Must ensure that relevant training stipulated in the PGDs and evidence of completion is provided

- Must complete a CPPE “Declaration of Competence”
- Have appropriate indemnity insurance to provide this service
- Be aware of and operate within local protocols
- Reassessment of competence to deliver the Varenicline and Cytisinicline service is recommended every 3 years
- Must have a valid Disclosure Barring Check (DBS)
- All pharmacists and registered pharmacy technicians have to complete CPPE safeguarding level 2.
- Participating pharmacies will also be expected to participate in periodic updates, meetings and refresher training as and when required.

The pharmacy is to offer a user-friendly, non-judgmental, client-centred and confidential service.

- 5.2. **Clients excluded from the PGD criteria:** Pharmacists and technicians should explain the reason for exclusion and if they are referred by the Portsmouth Wellbeing Service they should refer the patient back to Portsmouth Wellbeing Service documenting action that has been taken on PharmOutcomes.
- 5.3. **Privacy:** The pharmacy should provide a sufficient level of privacy (at the level requirement for the provision of Advanced Services as detailed in The Pharmaceutical Services (Advanced and Enhances Services) (England) Directions 2013 as amended).
- 5.4. **Records:** The Varenicline and Cytisinicline PGD supply forms on PharmOutcomes provide a helpful aide memoir to ensure all relevant aspects are covered in the consultation and that only clients who meet the criteria set out in the approved PGD for the supply of Varenicline and Cytisinicline. The pharmacy must maintain appropriate records to ensure effective ongoing service delivery, audit and for payment purposes. Records will be confidential and must be stored securely and for a length of time in line with the relevant PGD requirements.
- 5.5. **Data Sharing:** Service Providers may need to share relevant information with other health care professionals and agencies, in line with locally determined confidentiality arrangements, including, where appropriate, the need for the permission of the client to share the information. As the service is commissioned by Portsmouth City Council, the Council is the Data Controller of the information collated.
- 5.6. **Equality and Diversity:** The service will comply with the Equality Act 2010. The service will be delivered in a way that is non-discriminatory and advances equality of opportunity for people from different communities. The service will be provided in a safe environment, free from discrimination, where all individuals are treated fairly with dignity and respect. The provider will have an Equality and Diversity policy in place which clearly demonstrates how equality and inclusion are embedded throughout the organisation.
- 5.7. **Interdependencies:** The Service cannot work in isolation and is required to work with partners to support the delivery of a smoking cessation service. The provider will maintain efficient working relationships with allied services, agencies and stakeholders to enhance the quality of care delivered and ensure the holistic nature of the service. Specifically, linkages will need to be established and maintained with the Portsmouth Wellbeing Service and local general practices.

6. Quality Standards

- 6.1. The Service Provider will have robust risk management process in place, including:

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- i. Incident reporting and investigation processes
- ii. Complaints processes.

6.2. **Serious incidents:** All serious untoward incidents must be reported to the local authority within 2 working days of the incident. The service must then provide an outlined report of the incident and its outcome within 45 days of notification of the incident.

Contact details for Public Health are E: publichealth@portsmouthcc.gov.uk.

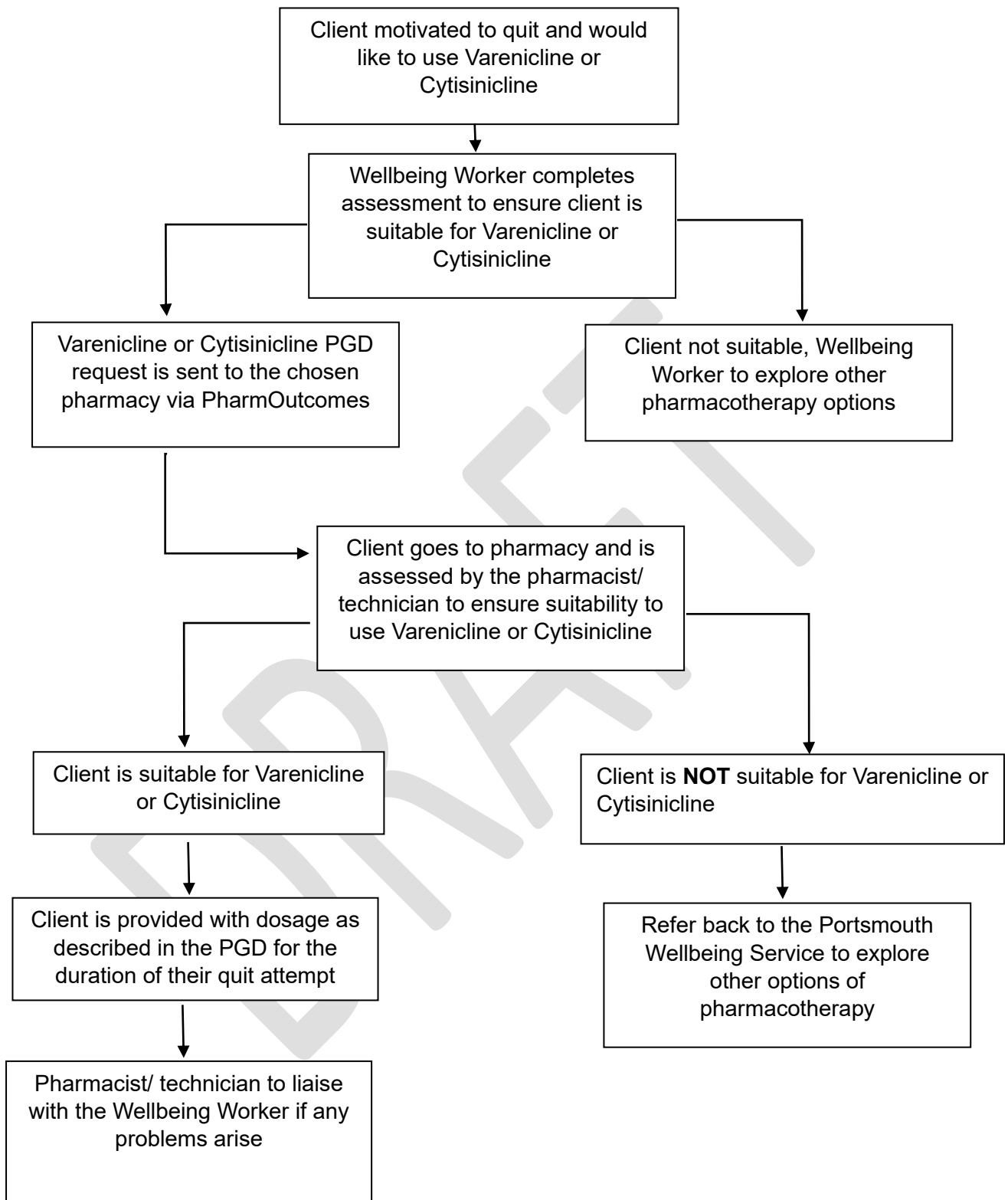
7. Payment

Payment for varenicline and Cytisinicline will be made monthly, in arrears based on activity recorded on the PharmOutcomes system. Payment will only be made via this process. No other payment method or request for payment can be accepted.

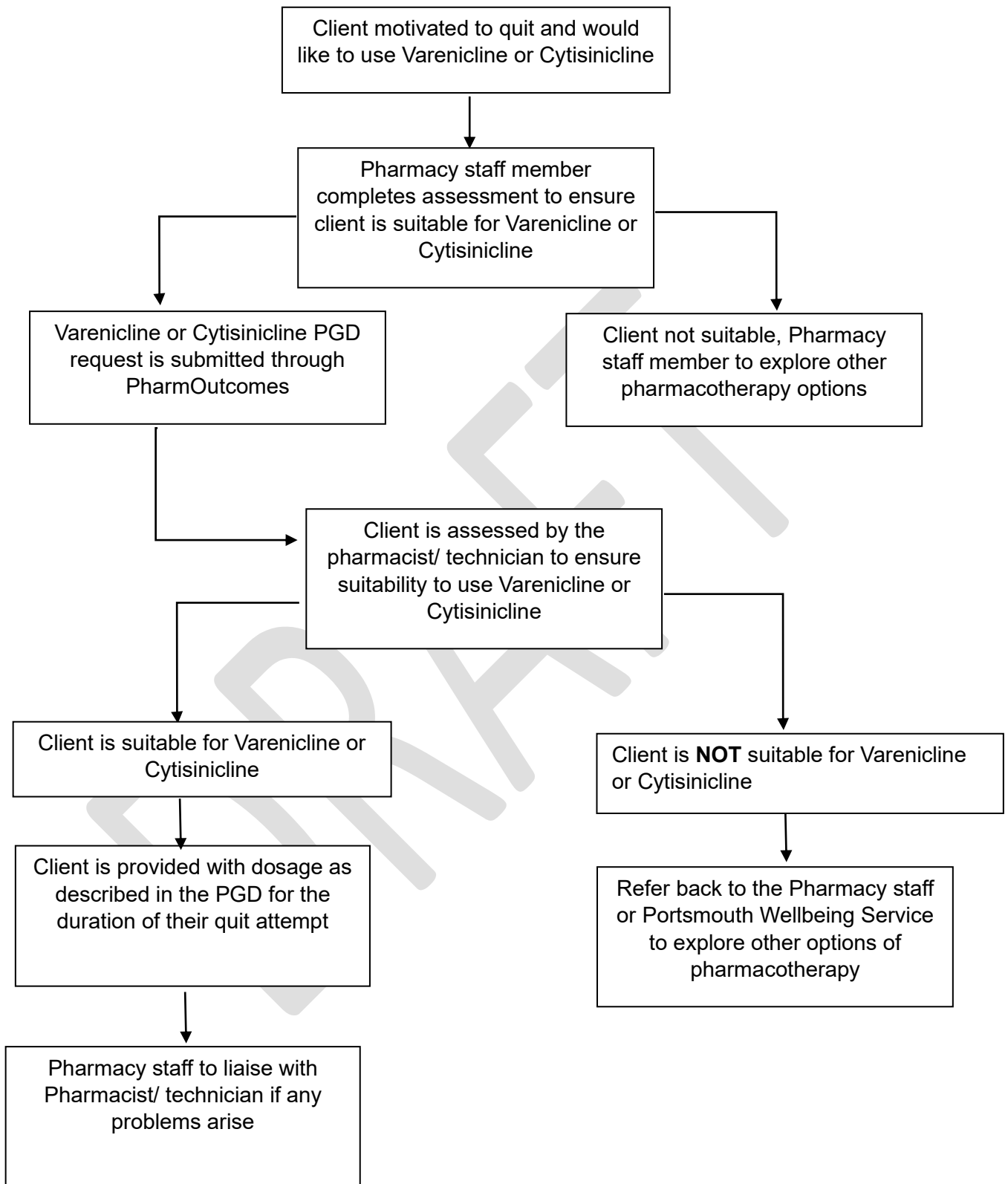
Payment will consist of:

Basis of Contract	Product	Unit of Measurement	Price (excluding VAT)
Activity	Varenicline	Varenicline at the shown cost on the DMD database plus 5% VAT	DMD
Activity	Cytisinicline	Cytisinicline at the shown cost on the DMD database plus 5% VAT	DMD
Activity	Varenicline and Cytisine	Initial Clinical Consultation	£20
Activity	Varenicline	Follow-up monitoring and supply contacts (x2 for 2 x monthly supplies)	£10

Appendix 1- Wellbeing Service Varenicline and Cytisinicline request flowchart



Appendix 2- Pharmacy Smoking Cessation Service Varenicline and Cytisinicline request flowchart



Appendix 3 - Exclusion criteria

Varenicline	Cytisinicline
<p>Individual</p> <ul style="list-style-type: none"> ● Consent to treatment refused and/or consent refused to share information with the individual's registered GP Practice ● Individuals under 18 years of age ● Individuals receiving varenicline and/or tobacco dependence treatment (i.e. Cytisinicline (Cytisine) or bupropion) from another provider ● Individuals who have no intention to stop smoking ● Individuals who report they are not sufficiently motivated to stop smoking or who are not willing to continue a course of treatment for (at least) 12 weeks and engage in behavioural support. ● Individuals unable to absorb oral medications and/or inability to swallow solid oral dosage formulations (i.e. tablets) <p>Pharmaceutical</p> <ul style="list-style-type: none"> ● Known hypersensitivity to varenicline or any of the components within the formulation – see Summary of Product Characteristics ● Previous intolerable adverse effects with varenicline use, that were not managed by dose reduction ● Previous Stevens-Johnson Syndrome or Erythema Multiforme associated with varenicline use <p>Medical</p> <ul style="list-style-type: none"> ● Individuals taking clozapine ● Known or suspected pregnancy (or pregnancy planned during treatment period) [See NICE NG209 guidance for information on recommended tobacco dependence treatment interventions in pregnant individuals]. ● Currently breastfeeding ● History of seizures or conditions known to lower the seizure threshold ● Known or suspected end stage renal disease (CKD stage 5, eGFR <15mL/min/1.73m²) 	<p>Individual</p> <ul style="list-style-type: none"> ● Consent to treatment refused and/or consent refused to share information with the individual's registered GP Practice ● Individuals under 18 years of age or aged 66 years and over ● Individuals receiving Cytisinicline and/or tobacco dependence treatment (i.e. varenicline or bupropion) from another provider ● Individuals who have no intention to stop smoking ● Individuals who report they are not sufficiently motivated to stop smoking or who are not willing to continue a course of tobacco dependence treatment for 25 days and engage in behavioural support. ● Individuals who have experienced tobacco dependence treatment failure with Cytisinicline in the last 2 months (i.e. have received treatment with Cytisinicline in the last 2 months). ● Individuals unable to absorb oral medications and/or inability to swallow solid oral dosage formulations (i.e. tablets) <p>Pharmaceutical</p> <ul style="list-style-type: none"> ● Known hypersensitivity to Cytisinicline or any of the components within the formulation – see Summary of Product Characteristics (SmPC) which can be accessed on the EMC website ● Previous intolerable adverse reactions with Cytisinicline ● Concurrent use of any interacting medicine as listed in Drug Interactions section of the PGD <p>Medical</p> <ul style="list-style-type: none"> ● Individuals taking clozapine ● Known or suspected pregnancy (or pregnancy planned during treatment period) See NICE NG209 guidance for information on recommended tobacco dependence treatment interventions in pregnant individuals. ● Currently breastfeeding ● Individuals of childbearing potential unable to use barrier method of contraception while taking Cytisinicline ● Unstable angina as detailed on the NHS website (symptoms persist despite resting) ● History of recent (in the previous 48 hours) myocardial infarction as detailed on the NHS website

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	<ul style="list-style-type: none">• History of recent (in the previous 48 hours) stroke as detailed on the NHS website• Clinically significant acute cardiac arrhythmias as detailed on the NHS website requiring hospitalisation• Known or suspected renal impairment (Chronic Kidney Disease (CKD) stages 2, 3a, 3b, 4 or 5 (eGFR <90ml/min/1.73m²))• Known or suspected hepatic impairment (i.e. ALT or AST > 2 X ULN)
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