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|  | **Provision of prescribed medications for the West Northamptonshire Council’s stop smoking service** |
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| 1. **Purpose**
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| This specification is part of the contractual relationship between West Northamptonshire Council (the Council) and the Service Provider for the delivery of consultation, assessment and supply of prescribed medications for smoking cessation, Cytisine and Varenicline.The aim of the service is to increase the access to treatment options for smokers who wish to quit smoking. |
| 1. **Background**
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| NICE guidance1 recommends two licensed prescription only medicines (POM) as defined by the Medicines Act 1968 and Prescription Only Medicines (Human Use) Order 1997. These are Varenicline and Cytisine. They are both subject to standard monitoring arrangements for adverse events via the Yellow Card Scheme. |
| 1. **Scope**
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This contract relates solely to the provision of Varenicline or Cytisine, via online pharmacy under a Patient Group Directions (PGD) or through an online GP service, for those patients who have been referred by West Northamptonshire’s Stop Smoking Service. * 1. **Aims and objectives of service**

The purpose of this service is to enable easy and equitable access to Varenicline (Champix) and Cytisine. The aim is that through ease of access to appropriate stop smoking treatments the service will contribute towards a reduction in smoking prevalence across West Northamptonshire by supporting high quality stop smoking service provision.The objectives of the service are to: * improve access to and choice of Stop Smoking services, specifically access to pharmacological smoking cessation aids;
* assist in the delivery of local smoking cessation targets;
* reduce smoking related illnesses and deaths by helping people to give up smoking;
* improve the health of the population by reducing passive exposure to smoke.

 **3.3 Population covered**Clients accessing the West Northamptonshire Stop Smoking Service, who are fulfilling the criteria set out in the West Northamptonshire Stop Smoking Service protocol, and who are referred to the Service by their Stop Smoking advisor.* 1. **Any acceptance and exclusion criteria and thresholds**

This Service will provide access to Varenicline (Champix), as it is available, and Cytisine. This will be through an online pharmacy through a Patient Group Direction or via an online GP service. Those eligible for the service are:Smokers aged 18 and over who are attending West Northamptonshire’s stop smoking service and have been assessed as sufficiently motivated to quit and have been referred to the service for Varenicline or Cytisine. Overall clinical responsibility for the supply of Varenicline and Cytisine lies with the clinician at the time of supply. As the legal responsibility for issuing the product rests with the pharmacist the final choice of formulation is at the discretion of the pharmacist. Prescribing guidelines must be followed for the provision of Varenicline and Cytisine.* 1. **Interdependencies with other services**

The West Northamptonshire Stop Smoking Service will provide one to one or group support for clients who wish to stop smoking. This includes setting a target quit date and providing NRT products and/or e-cigarettes. This contract will enable the service to also include Cytisine or Varenicline via a referral to an online service provision.* 1. **Any activity planning assumptions**

This Service will work in conjunction with the West Northamptonshire Stop Smoking Service as detailed in this specification.The Provider will have in place robust systems for the identification, mitigation and management of clinical and non-clinical risk. |
| 1. **Service Provision**
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| * 1. **Stop Smoking Advisors**

The customer will have seen a stop smoking advisor, who will assess the Service User's motivation to quit and provide ongoing one to one motivational support throughout the quit attempt. If the Service User expresses a preference for Varenicline or Cytisine the Stop Smoking Adviser will conduct an initial assessment for suitability and, if there are no contra-indications, refer the Service User to the service provider via Quit Manager or an online form.The Stop Smoking Adviser must explain to the Service User that it will be the clinician’s decision whether or not Varenicline or Cytisine is suitable option.**4.2 The Service Provider**Following referral, the Service Provider will contact the service user and provide an online appointment (via phone, Zoom, Microsoft Teams, or similar application) with a suitably qualified member of staff to assess the service user’s eligibility for Varenicline or Cytisine within 2 working days. The appointment must take place within 5 working days.If eligible, the Service Provider will post the medicine to the service user, following guidance on posting licensed medications.The Service Provider must ensure that all clinician’s involved in the provision of the service operate within clinical guidelines. If a pharmacist is dispensing the medicine this will be undertaken under a Patient Group Directive based on the Specialist Pharmacist Service framework.The Service Provider must assess the Service User for suitability for treatment and record the outcome in an agreed format with the Stop Smoking Service’s Quit Manager portal.In every case the Service Provider must inform the Service User's General Practitioner of the supply within two working days using an agreed template.If the outcome of the initial assessment is to not supply Varenicline or Cytisine the Service Provider must inform the Stop Smoking Service so that an alternative treatment may be offered.If Varenicline or Cytisine is withdrawn at any stage the Service Provider must inform the Service User's Stop Smoking Service within 2 working days so that an alternative treatment may be offered.The Service Provider shall maintain a record of supply using an agreed recording system, which is currently Quit Manager. The Service Provider should update this at each appointment to provide an ongoing information about the client's most recent appointment.The pharmacist must supply medicines in an appropriately labelled pack, including the Patient Information Leaflet. |
| 1. **Applicable Service Standards**
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| * 1. **Applicable national standards (e.g. NICE)**

The service is evidence based and must be delivered in accordance with the following: • [Surveillance decision | Evidence | Tobacco: preventing uptake, promoting quitting and treating dependence | Guidance | NICE](https://www.nice.org.uk/guidance/ng209/resources/2024-exceptional-surveillance-of-tobacco-preventing-uptake-promoting-quitting-and-treating-dependence-nice-guideline-ng209-13312648045/chapter/Surveillance-decision?tab=evidence#:~:text=7%2C%201.12.,as%20a%20stop%2Dsmoking%20intervention.) NICE Guidance - PH10 “Smoking cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach communities.”• NICE Technology Appraisal - TA123 “Varenicline for smoking cessation”• NICE Guidance - PH1 “Brief Interventions and Referral for smoking cessation in primary care and other settings”* Care Quality Commission’s Essential standards of quality and safety <http://www.cqc.org.uk/sites/default/files/documents/gac_-_dec_2011_update.pdf>

The service provider must also comply with Standards for registered pharmacies as set out by the General Pharmaceutical Council/ General Medical Council as well as qualities set out by NHS England.The service provider must comply with the requirements of the Equality Act 2010, and will not treat one group of people less favourably than others because of their age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, religion and belief, sex or sexual orientation.* 1. **Applicable local standards and terms of service**

The service provider will operate and provide the service in accordance with this specification unless altered/changed by agreement with the Council.A contract agreement will be signed by the service provider and will be subject to operational and performance review by the Council. * 1. **Service standards and principles**

The Service Provider will ensure that Standard Operating Procedures (SOPs) are in po do so.lace for the service and ensure that all clinican’s and members of staff involved in delivering the service are aware of them and work in accordance with them. The Service Provider shall keep and retain a record of all training activity and make it available to the Council for inspection when required tService Users will be seen as individuals, and the Service will be personalised to the needs of the individual and dedicated to promoting the independence, well-being and dignity of every Service User who engages with the Service.The Service will be accessible to all and will take account of culture, religion, race, gender, age, disability and sexuality. The Service Provider will ensure that it meets legal obligations with regards to all relevant equality and human rights legislation.The Service Provider will ensure that information acquired during the course of providing the Service is only shared and disclosed with the consent of the Service User as outlined in the NHS code of confidentiality and other associated documents.The Service Provider will ensure that there are necessary safeguards for, and appropriate use of, Service User and personal information to ensure that such information is dealt with legally, securely, efficiently and effectively, in order to deliver the best possible high quality care. This will be in accordance with relevant legislation and best practice guidelines such GDPR (2018) and the Caldicott Principles.The Service Provider will not make any changes to the Service, without prior written approval from the Council.Training and CompetencyFor pharmacists: In order to deliver the service on behalf of the Council pharmacists must:* be registered with the General Pharmaceutical Council (GPhC);
* be working in a pharmacy contracted to NHS England;
* Have completed relevant training, which includes:
	+ Attending the Varenicline Accreditation Event
	+ Attended a Cytisine Accreditation Event
	+ Knowledge of NICE Competency Framework for Health Professional using Patient Group Directions <http://publications.nice.org.uk/patient-group-directionsmpg2/recommendations#using-patient-group-directions>
	+ Completed the CPPE PGD Certificate
	+ Attended training in using Quit Manager
* Have adequate indemnity insurance to cover the tasks they are undertaking.
* Undertake Continuing Professional Development and to make this information available on request;
* 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 the individual practice.
* Make themselves familiar with the content of the Patient Group Direction for the supply of Varenicline and cytisine tablets.

For GPs:In order to deliver the service on behalf of the Council GPs must:* Hold a General Medical Service/PMS or APMS contract
* Have adequate indemnity insurance to cover the tasks they are undertaking.
* Complete training in how to use Quit Manger
* The clinician should be aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual clinician to keep up to date with continued professional development and to work within the limitations of the individual practice.
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| **6.0 Service Description** |
| * The Service Provider has a duty to ensure that all staff involved in the provision of this service have the relevant knowledge, skills and are appropriately trained in the provision of this service.
* The Service Provider has a duty to ensure that all staff involved in the provision of this service are aware of and act in accordance with local protocols and national guidance.
* Should the Service Provider have any concerns about the appropriateness of the recommended therapy they will discuss this with the the stop smoking advisor or service manager before making a supply and agree a course of action.
* The clinician should identify treatment options that have proven effectiveness and maximise commitment to the target quit date ensuring the client understands the ongoing support and monitoring arrangements and is provided with appropriate information and advice.
* The Service Provider should maintain appropriate records using Quit Manager to ensure ongoing service delivery and audit.
* The product(s) supplied must be labelled in accordance with the requirements of the Medicines, Ethics and Practice published by GPhC.

**6.1 Obligations of the service provider**The service provider must dispense Cytisine or Varenicline in accordance with timescales described in the Stop Smoking Service protocol. The service provider will record all information relating to the dispensing in the service users personal medical record and in Quit Manager. Staff responsible for the service must participate in any on-going training, review and competency assessment related to the service. The service provider will review its standard operating procedures (SOPs) and referral pathways for the service on an annual basis. The service provider will be able to demonstrate that all staff involved in the provision of the service have undertaken Continuing Professional Development (CPD) relevant to this service. The service provider will co-operate with any locally agreed audits and assessments of service user experience. The service provider will report any complaints to the Council.The service provider will co-operate with any audit of the service where there is reasonable evidence to suggest non-compliance with the terms of service.The Service Provider will have robust risk management process in place, including:* + Incident reporting and investigation processes
	+ Complaints processes.

The Service Provider will report all serious untoward incidents to the Council and provide details of recommendations and actions taken as a result.The Service Provider shall only charge the consultation and postage charges set out in their quote. The medication charges will be varied in line with the British National Formualry (BNF) as agreed with the Council.**6.2 Obligations of West Northamptonshire Council’s (WNC) Stop Smoking Service**The Council will provide a framework for recording relevant service information for the purposes of audit and claiming payment.The Council will be responsible for the promotion of the service locally including the development of publicity materials. The Council will provide details of allied services which staff can use to signpost clients who require further assistance. The Council will periodically review the service. The Council reserve the right to vary this contract if circumstances change. Variations will be made in writing. |
| **7.0 Access** |
| The Service will be available at a minimum Monday to Friday, 7am until 7pm. The Service will only be available to Service Users referred by Stop Smoking Advisers with the appropriate authority of the Council delivered or contracted Stop Smoking Service provider.The Service Provider will assess the suitability for a Service User to receive Varenicline or Cytisine to ensure they meet the clinical criteria.The service will be available to Service Users over 18 years of age who meet the inclusion criteria. |
| **8.0 Data Requirements and Record Keeping** |
| The service provider will be responsible for maintaining records for the period of time required by data protection legislation.Personal data must be protected in accordance with the provisions and principles of GDPR 2018.The service provider will maintain training records and self-declarations of competency in accordance with this specification and will show evidence of this to The Council as and when requested.The service provider must keep all records for a minimum period of 7 years. Electronic records must also be kept and available for this period. Records will be kept by the service provider in a secure and confidential manner. Records must be destroyed in a confidential manner.The consultation and its outcome should be recorded in Quit Manager. A brief outline of the Quit Manager system is provided in Appendix 1.Records maintained in association with this service must be made available to the Council on request for audit and verification purposes subject to prevailing data legislation provisions. |
| **Service Provision and Continuity**1 month before the service is to commence the Provider shall provide a mobilisation plan detailing as a minimum,* Arrangements for how you will deliver all elements of the service;
* A workforce plan including any training;
* The arrangements for suitable times and locations for service delivery or the details of how you will access appropriate populations;
* Clinical Governance arrangements, including management, clinical and safeguarding supervision and quality assurance;
* Safeguarding policies and procedures in line with National and Local Guidance;
* A Business Continuity Plan; and
* Proof of insurance.

It is the responsibility of the service provider to have a process in place which ensures that all new staff and locums are aware of all services provided by the pharmacy and commissioned by the Council and must maintain continuity of service during and after staff changes. The Service provider shall develop and maintain a business continuity plan that sets how it will maintain the service.**Monitoring and reporting**The Service Provider will be expected to report quarterly on the KPIs, set out below. The Service Provider shall provide a service narrative report to accompany the KPI report detailing key service highlights and achievements, challenges within the service and the associated mitigation, plus the key learning covering the content set out as a minimum the information detailed in Appendix 2. Quarterly meetings will be held with the Council to review the service.A quality and assurance document will be required quarterly to ensure the Council can be assured about the Service Provision as detailed in Appendix 2.Each year the Service Provider shall provide, in an agreed format, to the Council with an annual report setting out the last year’s activity. This report shall be provided by April 30th each year covering the previous April 1st to March 31st.**KPI’s**

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| **Performance indicator** |
| Number of people referred for Cytisine |
| Number of people given Cytisine |
| Number of people referred for Varenicline |
| Number of people given Varenicline |
| Average time taken to make contact with referrals |
| Average time taken to see referrals |
| Number of complaints (and copies of complaints and responses) |
| Number of people where the Service was declined |
| The reasons for the Service to be declined |

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1. **Appendixes and/or Annexes**

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| **No.** | **Document Name** |
|  | Appendix 1: Quit Manager |
|  | Appendix 2: Reporting requirement |

**Appendix 1: Quit Manager**

Quit Manager is a client/ patient management and reporting solution for stop smoking services. The Council has purchased Quit Manager and will give the Service Prover access to the system free of charge.

Quit Manager allows the storage of information about a clients stop smoking support and the treatment offered.

Special categories of data can be collected which includes health data like medical history and smoking history. It also includes information about a clients previous attempts to stop smoking, the current stop smoking plan and any treatment provided. Special categories of data also include ethnicity, gender, age and employment status. This helps the Council know which groups are using its services and whether some of them need extra help or support.

Quit Manager is also used as a picking and dispensing platform for treatment offered to clients. We are able to see what products have been requested and posted out to clients.

The Service Provider will be given access to Quit Manager to record the contact with a referred client, the result of the consultation(s) and the prescription of medication.

The Council shall provide training on Quit Manager to the Service Provider’s staff and provide the associated manuals and documentation for the system’s use for free.

**Appendix 2: Reporting requirement**

**Service provider report** **content requirement**

Service:

Provider:

Monitoring period:

Person completing the report:

Provider lead signed off:

**Report**

Overview covering:

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| **Aims and Objectives**   |
| **Key service highlights and positive achievements**  *i.e. what has gone well and resulted in positive outcomes for the service, what improvements have been implemented?*   |
| **Challenges within service affecting delivery and any mitigation**  *I.e. What is causing challenges within the service?*  *Is this affecting service delivery?*  *Are there associated/identified risks around these challenges?*  *What has been implemented to mitigate these risks/challenges?*  *How will this be reviewed and what is the timeline for this?*   |
| **Key Learning:**  Effectively highlight and record key learning points and incorporate them into improvement strategies during the project cycle and for future endeavours.    |
| **Focus for the next quarter:** What are the key focus areas for the next quarter?  |

**Progress against mobilisation/delivery/service development plan (operational report):**

* Actions set against timeline and progress against the actions

**Coms and marketing:**

* Show coms and marketing plan and provide a short narrative on progress, any areas of additional management and any implications the Council needs to be aware of.

**Finance:**

* Report on spend to date against profiled and total spend from agreement.
* Short narrative, any areas of additional management and any implications the Council needs to be aware of.

**Data:**

**Quantitative data**

* Progress against KPI’s set out in the agreement or otherwise agreed with the Council.
* Other quantitative data about the activity
* Short narrative, any areas of additional management and any implications the Council needs to be aware of.

**Qualitative data**

* Customer feedback
* Customer survey results
* Case studies
* Other engagement
* Complaints/Compliments
* Short narrative, any areas of additional management and any implications the Council needs to be aware of.

**Impact/outcome**

**Other operational information (workbook information as set out in the contract)**

Provide details of any,

* Incidents
* Policies and procedures where explicitly referenced, i.e. insurance
* Risk register
* Safeguarding etc.

**Quality and assurance report**

The Service Provider shall provide quality and assurance data each quarter in a format set out by the Council covering, but not be limited to,

* Insurance
* Business continuity
* Staffing and staff training
* Safeguarding, whistleblowing, complaints, incidents, accidents, information governance data, associated management and actions.
* Policies and procedures of the Service Provider relevant to the Service provision.

**Data Management / General Data Protection Regulation (GDPR)**

The Authority takes the processing of data seriously and applies security and privacy policies and procedures to ensure that all personal data within, or passing through the Authority, will be handled in accordance with the provisions of the appropriate UK GDPR, the Data Protection Act 2018, or any other legislation, regulation or other statutory instrument (the Data Protection Legislation).

Any Bidder who wishes to enter into a contract for the provision of goods, works or services with the Authority in which the processing of personal data is involved, must be able to demonstrate that they are fully compliant with the provisions of the Data Protection Legislation.

Any Bidder required to comply with the provisions of the Data Protection Legislation may incur costs in doing so, especially where new systems or processes are required to be adopted. Bidders are reminded these costs are attributable to conducting business in the EU, and not supplying the UK public sector, and all Bidders are accordingly required to manage their own costs in relation to compliance.

The Authority will not accept any liability clause in any Contract that seeks to indemnify the Bidder, as data processor, against fines under the provisions of the Data Protection Legislation. The legal penalty regime under the Data Protection Legislation has been extended directly to data processors to ensure better performance and enhanced protection for personal data, and any indemnification of Bidders as data processors for any Data Protection Legislation breaches resulting in fines or court claims undermines these principles.