

NHS Standard Contract 2020/21

Particulars (Shorter Form)

Contract title / ref:

Patient Group Direction (PGD)

for the supply of

Varenicline (Champix ®) tablets

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(please do not send contracts to this email address)

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Contract Reference	Patient Group Direction (PGD) for the supply of Varenicline (Champix ®) tablets
DATE OF CONTRACT	1 st March 2020
SERVICE COMMENCEMENT DATE	1 st March 2020
CONTRACT TERM	18 months commencing 1 st March 2020
COMMISSIONERS	Hampshire County Council
CO-ORDINATING Commissioner	Hampshire County Council
PROVIDER	Solutions 4 Health Unit 1 Thames Court Reading RG1 8EQ

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CONTRACT

This Contract records the agreement between the Commissioners and the Provider and comprises

1. these **Particulars**;
2. the **Service Conditions (Shorter Form)**;
3. the **General Conditions (Shorter Form)**,

as completed and agreed by the Parties and as varied from time to time in accordance with GC13 (*Variations*).

IN WITNESS OF WHICH the Parties have signed this Contract on the date(s) shown below

SIGNED by
Signature

[INSERT AUTHORISED SIGNATORY'S NAME] for
Title
and on behalf of
Hampshire County Council
Date

[INSERT AS ABOVE FOR EACH COMMISSIONER]

SIGNED by
Signature

[INSERT AUTHORISED SIGNATORY'S NAME] for
Title
and on behalf of
[INSERT PROVIDER NAME]
Date

SERVICE COMMENCEMENT AND CONTRACT TERM	
Effective Date	1 st March 2020
Expected Service Commencement Date	1 st March 2020
Longstop Date	N/A
Service Commencement Date	1 st March 2020
Contract Term	18 months commencing 1 st March 2020
Option to extend Contract Term	YES
Notice Period (for termination under GC17.2)	1 month
SERVICES	
Service Categories	Indicate <u>all</u> that apply
Continuing Healthcare Services (including continuing care for children) (CHC)	
Community Services (CS)	Yes
Diagnostic, Screening and/or Pathology Services (D)	
End of Life Care Services (ELC)	
Mental Health and Learning Disability Services (MH)	
Patient Transport Services (PT)	
Co-operation with PCN(s) in service models	
Enhanced Health in Care Homes	NO
Service Requirements	
Essential Services (NHS Trusts only)	NO
Is the Provider acting as a Data Processor on behalf of one or more Commissioners for the purposes of the Contract?	NO
PAYMENT	

National Prices Apply to some or all Services (including where subject to Local Modification or Local Variation)	YES
Local Prices Apply to some or all Services	NO
Expected Annual Contract Value Agreed	NO
GOVERNANCE AND REGULATORY	
Provider's Nominated Individual	Dr Asiya Kaiser Address: Solutions 4 Health Unit 1 Thames Court Reading RG1 8EQ Email: asiya.kaiser@solutions4health.co.uk
Provider's Information Governance Lead	As above
Provider's Data Protection Officer (if required by Data Protection Legislation)	As above
Provider's Caldicott Guardian	As above
Provider's Senior Information Risk Owner	As above
Provider's Accountable Emergency Officer	As above
Provider's Safeguarding Lead	As above
Provider's Child Sexual Abuse and Exploitation Lead	As above
Provider's Mental Capacity and Liberty Protection Safeguards Lead	As above
Provider's Freedom To Speak Up Guardian(s)	As above
CONTRACT MANAGEMENT	
Addresses for service of Notices	Co-ordinating Commissioner: Hampshire County Council Address: The Castle, Winchester SO23 8UJ Email: ***
Commissioner Representative(s)	[] Address: [] Email: [] Tel: []
Provider Representative	Dr Asiya Kaiser Address: Solutions 4 Health Unit 1 Thames Court

	Reading RG1 8EQ Email: asiya.kaiser@solutions4health.co.uk
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SCHEDULE 1 – SERVICE COMMENCEMENT AND CONTRACT TERM

A. Conditions Precedent

The Provider must provide the Co-ordinating Commissioner with the following documents and complete the following actions:

1. Evidence of appropriate Indemnity Arrangements
2. [Evidence of CQC registration (where required)]
3. [Evidence of Monitor's Licence (where required)]
4. [Copies of the following Sub-Contracts signed and dated and in a form approved by the Co-ordinating Commissioner] *[LIST ONLY THOSE REQUIRED FOR SERVICE COMMENCEMENT AND NOT PROVIDED ON OR BEFORE THE DATE OF THIS CONTRACT]*
5. [Insert text locally as required]

C. Extension of Contract Term

To be included only in accordance with the Contract Technical Guidance.

1. [As advertised to all prospective providers during the competitive tendering exercise leading to the award of this Contract], the Commissioners may opt to extend the Contract Term by [] months/year(s).
2. If the Commissioners wish to exercise the option to extend the Contract Term, the Co-ordinating Commissioner must give written notice to that effect to the Provider no later than [] months before the original Expiry Date.
3. The option to extend the Contract Term may be exercised:
 - 3.1 only once, and only on or before the date referred to in paragraph 2 above;
 - 3.2 only by all Commissioners; and
 - 3.3 only in respect of all Services
4. If the Co-ordinating Commissioner gives notice to extend the Contract Term in accordance with paragraph 2 above, the Contract Term will be extended by the period specified in that notice and the Expiry Date will be deemed to be the date of expiry of that period.

Or

NOT USED

SCHEDULE 2 – THE SERVICES

A. Service Specifications

1. National context

The Tobacco Control Plan for England (2017-22) has the following targets

- (A) Reduce the prevalence of 15-year olds who regularly smoke from 8% to 3% or less by the end of 2022.
- (B) Reduce smoking prevalence amongst adults in England from 15.5% to 12% or less by the end of 2022
- (C) Reduce the inequality gap in smoking prevalence between those in routine and manual occupations and the general population by the end of 2022.
- (D) Reduce the prevalence of smoking in pregnancy from 10.7% to 6% or less by the end of 2022

Local context

In 2017 it was estimated that in Hampshire 14.4% of the adult population were current smokers equating to 155,414 (18+) smoking. However, estimated rates vary greatly across local districts ranging from; Havant:21.4%, Gosport 19.6%, Rushmoor 18.4%, Basingstoke & Deane 16.9% down to Winchester 11.5%, and Hart and East Hampshire are the lowest two at 7.8% and 7.7% respectively (PHOF: Local Tobacco Control Profiles, July 2018)

2. Eligibility:

Clients must:

- Have been referred to the pharmacist by the Smokefree Hampshire service
- One of the following: 1) be a resident of Hampshire County Council 2) is registered with the Hampshire GP surgery or 3) works within Hampshire (excluding Southampton City, Portsmouth City, IOW).
- Dependent tobacco users identified as sufficiently motivated to quit with Varenicline or are allergic to nicotine or any excipients of Nicotine Replacement Therapy products.
- Be aged 18 and over
- Eligible under the terms of the PGD risk assessment
- Agree to the therapy and attend all 12 weeks for behavioural advice and follow up carbon monoxide checks with Smokefree Hampshire staff
- Patient consent has been obtained for treatment and recorded.
- Patient has consented for information to be shared with their GP, “Smokefree Hampshire” service as recorded on the Quit Manager, along with forms 1, 2, and 4 with the stop smoking advisor and PGD

accredited pharmacist (see appendix: A for supplementary forms on page:15).

- “Smokefree Hampshire” service stop smoking advisor will give form 5 to the patient based on their progression through their quit attempt. Patient must attend their nominated PGD accredited Varenicline pharmacy where they will be seen by the PGD accredited pharmacist
- Supplies after the first titration pack can only be made if the client continues to attend the “Smokefree Hampshire” Specialist Smoking Cessation Service sessions on a weekly basis for a face to face consultation with the stop smoking advisor. The supplying pharmacist will be notified of this through the provision of form 5 for maintenance supplies, which will be issued by the stop smoking advisor on a fortnightly basis.
- “Smokefree Hampshire” service stop smoking advisor must not hesitate to contact the pharmacist through telephone or email if required to discuss the patient’s progression through the quit attempt along with any relevant issues or concerns which may need to be highlighted.
- Pharmacists are working as part of the wider healthcare team providing support for smoking cessation and should not feel isolated. Pharmacists can contact Smokefree Hampshire colleagues if need be for further advice.

Exclusion criteria:

- Tobacco users not sufficiently motivated to quit or use Varenicline.
- Patient has had an unsuccessful attempt to quit using Varenicline on the programme in the last 6 months.
- Patient is under the age of 18.
- Hypersensitivity to Varenicline or any of the product excipients (check manufacturer’s SPC for details).
- Patients with a history of, or current moderate to severe renal impairment.
- Pregnant or breastfeeding women.
- Valid consent not provided.
- Patient not registered with a GP.
- No consent to share information with GP.
- Other licensed smoking cessation therapies (i.e. nicotine replacement therapy products) currently being used by the patient. These will need to be discontinued before patient can be considered for Varenicline.
- Clients taking bupropion (Zyban®).
- Clients currently obtaining varenicline on prescription or under PGD from another health professional.
- Clients with current unstable psychiatric illness such as Schizophrenia, Bipolar disorder and major depressive disorder.

- Patients with a history of seizures or with other conditions that lower the seizure threshold.
- Patients with active unstable cardiovascular disease or who have had a recent cardiovascular event in the past 3 months.

3. AIMS AND OBJECTIVES

The objectives are to provide a Champix/Varenicline supply service for Hampshire that:

- Offers timely, accessible and evidence-based treatment and behavioural support to people who want to quit smoking
- Engages partners effectively to actively promote stop smoking support through their contact with local people
- Work with health professionals and other partners to increase awareness in local communities of the benefits associated with quitting and smoke-free environments

4. SCOPE OF THE SERVICE

- FREE Training and support to deliver the signed PGD will be provided by Smokefree Hampshire service via the course for pharmacists, which covers; very brief advice, marketing materials, varenicline overview and PGD documents
- Clients will be referred to the service by Smokefree Hampshire and must have a valid referral document (Form 5)
- The pharmacist will undertake the risk assessment as set out in the PGD (Form 1)
- Champix/Varenicline only should be provided to the service user under the PGD and recorded using Form 1
- Returns should be sent monthly via completion of Form 1A

5. Support available from Smokefree Hampshire

Primary Care Providers can access the following support from Smokefree Hampshire to support the delivery of this service:

- **FREE** Training for Pharmacists
- Supply of promotional material

6 PRINCIPLES AND STANDARDS

6.1 Principles of the Service

6.1.1 The aim of the Dignity in Care campaign, launched by the Department of Health 2006, is to put dignity and respect at the heart of all health and

care services. It states that all high-quality services should embody and be mindful of the 10-point Dignity Challenge:

- Have a zero tolerance of all forms of abuse
- Support people with the same respect you would want for yourself or a member of your family
- Treat each person as an individual by offering a personalised service
- Enable people to maintain the maximum possible level of independence, choice and control
- Listen and support people to express their needs and wants
- Respect people’s right to privacy
- Ensure people feel able to complain without fear of retribution
- Engage with family members and carers as care partners
- Assist people to maintain confidence and positive self esteem
- Act to alleviate people’s loneliness and isolation

6.2 Standards of the Service

- If a Pharmacist leaves the Pharmacy or does not want to continue providing the service, Smokefree Hampshire should be informed immediately
- Champix provision should only be delivered by Pharmacists accredited by Smokefree Hampshire and meeting the DH intervention quality principles.

7. MONITORING PERFORMANCE

7.1 Review

- Smokefree Hampshire will undertake the performance management of this service.

7.2 Audit checks

- Smokefree Hampshire will carry out audit checks to ensure the quality of the interventions.

8 FINANCIAL

- Pharmacy to invoice “Smokefree Hampshire” every month. Invoices must reach “Smokefree Hampshire” by the 1st of every month for processing.
- Invoices will be paid within 30 days once received and processed by Smokefree Hampshire.
- If pharmacy has continued to dispense Varenicline under the PGD to those patients who relapsed during the treatment programme, Smokefree Hampshire will not be held responsible for picking up the cost of Varenicline.

- Failure to adhere to above rules will result in rejection of payment and immediate suspension of PGD for the particular pharmacist who breached the above rules.

Payment details:

Initial registration and starter pack supply (14 days) of varenicline via PGD:

- £4 service fee + £10 one-off consultation fee + Champix® drug tariff cost (5% VAT) minus NHS prescription levy charge (if patient pays levy prescription charge).

Varenicline PGD stage 2 (supply and advice for follow up appts):

- £4 service fee for a fortnightly supply (there may be 2 supplies during month) + Champix® drug tariff cost (5% VAT), minus NHS prescription levy charge (if patient pays levy prescription charge).

Associated documents:



PGD varenicline
Hampshire Feb 2020

SCHEDULE 2 – THE SERVICES

SCHEDULE 2 – THE SERVICES

B. Indicative Activity Plan

Not Applicable

D. Essential Services (NHS Trusts only)

Not Applicable

G. Other Local Agreements, Policies and Procedures

Not Applicable

J. Transfer of and Discharge from Care Protocols

Not applicable

K. Safeguarding Policies and Mental Capacity Act Policies



S4H GEN POL 003a
Safeguarding Declai



S4H GEN POL 068
Mental Capacity Poli

SCHEDULE 3 – PAYMENT

A. Local Prices

- Pharmacy to invoice “Smokefree Hampshire” every month. Invoices must reach “Smokefree Hampshire” by the 1st of every month for processing.
- Invoices will be paid within 30 days once received and processed by Smokefree Hampshire.
- If pharmacy has continued to dispense Varenicline under the PGD to those patients who relapsed during the treatment programme, Smokefree Hampshire will not be held responsible for picking up the cost of Varenicline.
- Failure to adhere to above rules will result in rejection of payment and immediate suspension of PGD for the particular pharmacist who breached the above rules.

Payment details:

Initial registration and starter pack supply (14 days) of varenicline via PGD:

- £4 service fee + £10 one-off consultation fee + Champix® drug tariff cost (5% VAT) minus NHS prescription levy charge (if patient pays levy prescription charge).

Varenicline PGD stage 2 (supply and advice for follow up appts):

- £4 service fee for a fortnightly supply (there may be 2 supplies during month) + Champix® drug tariff cost (5% VAT), minus NHS prescription levy charge (if patient pays levy prescription charge).

B. Local Variations

For each Local Variation which has been agreed for this Contract, copy or attach the completed publication template required by NHS Improvement (available at: <https://improvement.nhs.uk/resources/locally-determined-prices/>) – or state Not Applicable. Additional locally-agreed detail may be included as necessary by attaching further documents or spreadsheets.

Not Applicable

C. Local Modifications

For each Local Modification Agreement (as defined in the National Tariff) which applies to this Contract, copy or attach the completed submission template required by NHS Improvement (available at: <https://improvement.nhs.uk/resources/locally-determined-prices/>). For each Local Modification application granted by NHS Improvement, copy or attach the decision

notice published by NHS Improvement. Additional locally-agreed detail may be included as necessary by attaching further documents or spreadsheets.

Not Applicable

F. Expected Annual Contract Values

Not Applicable

(Specify the proportion of the Expected Annual Contract Value to be invoiced each month, in accordance with SC36.21.)

(In order to be able to demonstrate compliance with the Mental Health Investment Standard and with national requirements for increased investment in Primary Medical and Community Services, ensure that the indicative values for the relevant services are identified separately below. For guidance on the definitions which apply in relation to the Mental Health Investment Standard, see Categories of Mental Health Expenditure. Guidance in relation to primary medical and community services has been published as part of the NHS Operational Planning and Contracting Guidance 2020/21 and is available via Sharepoint.)

SCHEDULE 4 – QUALITY REQUIREMENTS

A. Operational Standards and National Quality Requirements

Ref	Operational Standards/National Quality Requirements	Threshold	Guidance on definition	Consequence of breach	Timing of application of consequence	Applicable Service Category
E.B.4	Percentage of Service Users waiting 6 weeks or more from Referral for a diagnostic test	Operating standard of no more than 1%	See <i>Diagnostics Definitions and Diagnostics FAQs</i> at: https://www.england.nhs.uk/statistics/statistical-work-areas/diagnostics-waiting-times-and-activity/monthly-diagnostics-waiting-times-and-activity/	Where the number of Service Users waiting for 6 weeks or more at the end of the month exceeds the tolerance permitted by the threshold, £200 in respect of each such Service User above that threshold	Monthly	CS D
E.B.S.3	The percentage of Service Users under adult mental illness specialties who were followed up within 72 hours of discharge from psychiatric in-patient care	Operating standard of 80%	See <i>Contract Technical Guidance Appendix 3</i>	Where the number of Service Users in the Quarter not followed up within 72 hours exceeds the tolerance permitted by the threshold, £200 in respect of each such Service User above that threshold	Quarterly	MH

Ref	Operational Standards/National Quality Requirements	Threshold	Guidance on definition	Consequence of breach	Timing of application of consequence	Applicable Service Category
	Duty of candour	Each failure to notify the Relevant Person of a suspected or actual Notifiable Safety Incident in accordance with Regulation 20 of the 2014 Regulations	See CQC guidance on Regulation 20 at: https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour	Recovery of the cost of the episode of care, or £10,000 if the cost of the episode of care is unknown or indeterminate	Monthly	All
E.H.4	Early Intervention in Psychosis programmes: the percentage of Service Users experiencing a first episode of psychosis or ARMS (at risk mental state) who wait less than two weeks to start a NICE-recommended package of care	Operating standard of 60%	See Guidance for Reporting Against Access and Waiting Time Standards and FAQs Document at: https://www.england.nhs.uk/mental-health/resources/access-waiting-time/	Issue of Contract Performance Notice and subsequent process in accordance with GC9	Quarterly	MH
E.H.1	Improving Access to Psychological Therapies (IAPT) programmes: the percentage of Service Users referred to an IAPT programme who wait six weeks or less from referral to entering a course of IAPT treatment	Operating standard of 75%	See Annex F1, NHS Operational Planning and Contracting Guidance 2020/21 at: https://www.england.nhs.uk/publication/nhs-operational-planning-and-contracting-guidance-2020-21-	Issue of Contract Performance Notice and subsequent process in accordance with GC9	Quarterly	MH

Ref	Operational Standards/National Quality Requirements	Threshold	Guidance on definition	Consequence of breach	Timing of application of consequence	Applicable Service Category
			<u>annex-f-activity-and-performance/</u>			
<i>E.H.2</i>	<i>Improving Access to Psychological Therapies (IAPT) programmes: the percentage of Service Users referred to an IAPT programme who wait 18 weeks or less from referral to entering a course of IAPT treatment</i>	<i>Operating standard of 95%</i>	<i>See Annex F1, NHS Operational Planning and Contracting Guidance 2020/21 at: <u>https://www.england.nhs.uk/publication/nhs-operational-planning-and-contracting-guidance-2020-21-annex-f-activity-and-performance/</u></i>	<i>Issue of Contract Performance Notice and subsequent process in accordance with GC9</i>	<i>Quarterly</i>	<i>MH</i>

The Provider must report its performance against each applicable Operational Standard and National Quality Requirement through its Service Quality Performance Report, in accordance with Schedule 6A.

In respect of the Operational Standards and National Quality Requirements shown in ***bold italics*** the provisions of SC36.28 apply.

SCHEDULE 4 – QUALITY REQUIREMENTS

C. Local Quality Requirements

Quality Requirement	Threshold	Method of Measurement	Consequence of breach	Timing of application of consequence	Applicable Service Specification
Robust standard operating procedure in place	Evidence of SOP in place	Quarterly audit	Action plan to investigate & address any issues	quarterly	Schedule 2
All pharmacists have received minimum standard of training	Minimum training standard	Quarterly audit	Remedial action plan to address training needs	quarterly	Schedule 2
Pharmacists will complete the paper declaration of competency prior to providing this service as outlined in section: 6 of the PGD	Minimum training standard	Quarterly audit	Unable to deliver the service	immediate	Schedule 2

SCHEDULE 4 – QUALITY REQUIREMENTS

D. Commissioning for Quality and Innovation (CQUIN)

EITHER:

CQUIN Table 1: CQUIN Indicators

N/A

OR:

The Commissioners have applied the small-value contract exception set out in CQUIN Guidance and the provisions of SC38.8 therefore apply to this Contract.

SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

A. Reporting Requirements

	Reporting Period	Format of Report	Timing and Method for delivery of Report
National Requirements Reported Centrally			
1. As specified in the DCB Schedule of Approved Collections published on the NHS Digital website at https://digital.nhs.uk/isce/publication/nhs-standard-contract-approved-collections where mandated for and as applicable to the Provider and the Services	As set out in relevant Guidance	As set out in relevant Guidance	As set out in relevant Guidance
National Requirements Reported Locally			
1. Activity and Finance Report (<i>note that, if appropriately designed, this report may also serve as the reconciliation account to be sent by the Provider under SC36.22</i>)	Monthly	Invoices sent to Smokefree Hampshire	monthly
2. Service Quality Performance Report, detailing performance against Operational Standards, National Quality Requirements, Local Quality Requirements, Never Events and the duty of candour	[For local agreement, not less than quarterly]	[For local agreement]	[For local agreement]
	[For local agreement]	[For local agreement]	[For local agreement]
3. Complaints monitoring report, setting out numbers of complaints received and including analysis of key themes in content of complaints	[For local agreement, not less than annually]	[For local agreement]	[For local agreement]
4. Summary report of all incidents requiring reporting	[For local agreement, not less than annually]	[For local agreement]	[For local agreement]
Local Requirements Reported Locally			
Pharmacists will keep a record of their consultations on supplementary paper forms and will record Varenicline supplies on form 1. Pharmacies must participate in an annual clinical audit if requested by the service provider.	monthly	Form 1	Monthly

SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

C. Incidents Requiring Reporting Procedure

Procedure(s) for reporting, investigating, and implementing and sharing Lessons Learned from: (1) Serious Incidents (2) Notifiable Safety Incidents (3) Other Patient Safety Incidents

The Medicines and Health Products Regulatory Agency (MHRA) asks that all suspected reactions are reported through the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or via the yellow card found at the back of the current edition of the BNF. If reporting via the latter, please post the yellow card to: FREEPOST YELLOW CARD (no other address details required). ADRs should also be reported to the “Smokefree Hampshire” stop smoking advisor at the details given above, who will liaise with the GP to notify them, following client’s consent.

SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

F. Provider Data Processing Agreement

Not Applicable

SCHEDULE 7 – PENSIONS

Not Applicable

SCHEDULE 8 – TUPE*

1. NA

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