

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	
Service	Community Pharmacy – Antiviral Access Points – “In Season” and “Out of Season”
CCG Lead	Samiullah Choudhry –Head of Medicines Optimisation NHS Wakefield Clinical Commissioning Group
Provider Lead	TBC
Period	November 2021 – November 2023
Date of Review	August 2022

1. Population Needs		
<ul style="list-style-type: none"> National/local context and evidence base <p>This service covers the provision of the following in Community Pharmacy:</p> <p>The purpose of this service is for community pharmacies to stock and supply antivirals for the treatment and prophylaxis of influenza. This includes usual extended opening hours, including weekends.</p> <p>The purpose of this Locally Commissioned Service Specification is to:</p> <ul style="list-style-type: none"> Support the supply and delivery of antivirals for incidents of influenza Help prevent emergency hospital admissions Equip the commissioner (Wakefield CCG), service providers and practitioners with the necessary knowledge and prevent service and implementation delays to safely deliver this service. <p>Wakefield CCG requires the following in terms of Community Pharmacy location and opening hours:</p> <ul style="list-style-type: none"> Registered with the General Pharmaceutical Council Located in Wakefield (one in central Wakefield, the other can be within the surrounding area) Meeting the core contractual obligations required by the NHS England’s Area Team Operate a medicines delivery service - The pharmacy will deliver the antiviral medication to the required location –this could be to any site within Wakefield District (reimbursement form Appendix E). Contracted hours will be for a minimum of extended opening Monday to Saturday. Opening on a Sunday is desirable. 		
2.1 <u>NHS Outcomes Framework Domains & Indicators</u>		
Domain 1	Preventing people from dying prematurely	√
Domain 2	Enhancing quality of life for people with long-term conditions	√

Domain 3	Helping people to recover from episodes of ill-health or following injury	√
Domain 4	Ensuring people have a positive experience of care	√
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	√

2.2 Local defined outcomes

Preventative Treatment and reducing complications: Improving patient access to the antiviral medication, as directed by PHE Guidance:

[PHE Guidance](#)

3. Scope

3.1 Aims and objectives of service

The aim of the service is to increase prompt access for patients who require antiviral medication for influenza treatment/prophylaxis.

“In season” flu -- when national surveillance indicates influenza virus is circulating generally in the community. Usual route via an FP10 presented to the patients nominated pharmacy unless a large outbreak when patients may need to be directed to a specific pharmacy

“Out of season” flu -- outside the periods when national surveillance indicates that influenza virus is circulating generally in the community, there are no fixed dates.

3.2 Service description/care pathway

The service will be commissioned by Wakefield CCG for 2 years (with the option to extend for a further year) to provide the following:

- Commitment to stock a defined list of antiviral medication and to ensure prompt access
- Commitment to adhere to the required opening times as detailed in this service specification. Any proposed changes to opening hours after commencement of this service must be notified to NHSE&I within 90 days and to the Wakefield CCG Head of Medicines Optimisation as soon as possible.
- Signposting to other sources of support and advice as provided by the CCG.

The pharmacy is to hold a specified list of antiviral medication required to deliver this service (Appendix A). The list also includes the minimum stock levels required in the pharmacy to deliver this service. The stock levels are subject to regular review by the community pharmacist and the CCG lead in conjunction with Public Health England. The drug list is also subject to change with regards to availability of medication and change in clinical guidance This will be reflected in the contract alongside appropriate reimbursement.

The pharmacy must keep a stock of the specialised medicines at all times. Community Pharmacies will notify the CCG Head of Medicines Optimisation, if they are experiencing any difficulty in obtaining the required stock via the Medicines Optimisation email address

wakccg.medsoptwakefield@nhs.net

- **Population covered**

This service is available in the event of a localised outbreak in one or more locations involving numerous people e.g., care home. The service is open to patients in Wakefield as well as members of the public that are working in Wakefield, requiring antiviral treatment for flu treatment/prophylaxis, identified following clinical assessment.

3.4 Any acceptance and exclusion criteria and thresholds

Essential criteria

To be accepted onto the CCG's scheme pharmacies must be:

- Located within the Central Locality for Wakefield (and one from the surrounding areas)
- Meeting the core contractual obligations required by NHS England
- Operate a medicines delivery service - The pharmacy will deliver the antiviral medication to the required location –this could be to any site within Wakefield District
- Contracted hours will be for a minimum of extended opening Monday to Saturday. Opening on a Sunday is desirable.

Exclusion Criteria

- The scheme is not available to Community Pharmacies outside of the Wakefield district
- Distance Selling Pharmacies (DSPs)

Overall the CCG is looking to ensure accessibility to antiviral medication which would help prevent an emergency hospital attendance or admission for this cohort of patients. All eligible community pharmacies meeting the essential criteria are invited to express an interest.

In season arrangements are for patients, carer or patient representatives accessing the service by presenting a prescription to their usual nominated pharmacy.

3.5 Interdependence with other services/providers

The list of pharmacies prepared to offer this service is to be made available to the following service providers:

- GP Practices
- On-call out of hours service provider for GP practices
- Accident and Emergency Departments of local NHS hospitals
- NHS 111
- Turning Point
- Locality Walk-in Centres
- Angel Lodge – initial accommodation centre
- Hospices

The above providers under core contractual requirements will assess and arrange treatment of patients who are ill, or who believe themselves to be ill, with influenza like illness as this will fall within the definition of essential medical services and we would expect patients to be managed as such, in line with the requirements set out in provider contracts.

In addition to the above listed service providers, the following organisations will be made aware of the community pharmacies participating in this scheme:

- Other community pharmacies
- CCG Medicines Optimisation Team
- NHSE&I

4. Applicable Service Standards

4.1 Applicable national standards (e.g. NICE)

- Community Pharmacy Contractual Framework 2019-2024
- PHE guidance on use of antiviral agents for the treatment and prophylaxis of seasonal influenza version 10.0, September 2020
- The National Health Service (Pharmaceutical Services) Regulations 2012

- General Pharmaceutical Council. Standards for Pharmacy Professionals 2017 https://www.pharmacyregulation.org/sites/default/files/standards_for_pharmacy_professionals_may_2017_0.pdf
- Any other as appropriate to the services/staffing

The service shall be adapted or developed in response to new guidance, evidence-based practice and policy, including those as set out above.

Where a change in policy or guidance is likely to have a material impact on costs or practice, the Provider shall notify the Commissioner prior to any change in order to agree action as appropriate.

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

PHE Guidance in 2.2.

4.3 Applicable local standards

4.3.1. Record Keeping

The pharmacy is responsible for completing the normal legal records for the dispensing of prescription only medicines.

4.3.2. Information Collection

The pharmacy is required to monitor stock levels of the antiviral medication and ensure the agreed level of stock is available

Full records are to be maintained to allow for data and details to be readily accessible for inspection if required as per Appendix B

Confirmation of stock levels and expiry dates when service commences and then quarterly audits, see appendix B.

4.3.3. Training and Accreditation

No specialist training or accreditation is required over and above the normal requirements for a pharmacist providing dispensing services.

4.3.4. Adverse Incidents

Accredited pharmacists should report all adverse incidents that relate to this service through the usual pharmacy process as well as notifying the CCG through the Medicines Optimisation email address wakccg.medsoptwakefield@nhs.net

4.3.5. Governance

The pharmacy contractor should ensure only appropriately qualified and trained staff, including locums, should provide the service to the required professional and ethical standards of care and treatment. The community pharmacist is responsible for maintaining adequate staffing levels to provide the service and for maintaining their CPD (Continuing Professional Development).

The pharmacy contractor must ensure all staff, including locums, are aware of the service.

The contractor is required to comply with all relevant legislation and have regard to all relevant guidance including the current Safeguarding Children and Vulnerable Adults Policy.

As part of this, the pharmacy is required to have regard to the Department of Health's "Code of Confidentiality".

The CCG's Medicines Optimisation team may undertake a random check of stocks held by the contracted pharmacies

4.3.6. Key Performance Indicators (see section 9 for more details)

The contractor will be performance managed against the following:

- Maintaining and supplying the agreed list of medicines at the required levels.
- Meeting the submission requirements of this Service Specification e.g.' timely return of the quarterly reports. This will include current contact details of the member of staff who is identified as the 'Out of Season Antiviral Stock Controller' along with those members of staff who will deputise in their absence
- A reminder email will be sent one week before submission is due

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

Applicable quality requirements: The pharmacy contractor should ensure the following:

- All goods used in the performance of the agreement should be of a satisfactory quality and be fit for the purpose for which they are used
- The pharmacy has a complaints procedure for monitoring the services provided
- It co-operates with any reasonable review of the client experience.

5.2 Applicable CQUIN goals (See Schedule 4 Parts A-D)

Not applicable at this time.

6. Location of Provider Premises

The Provider's Premises are located at:

- Wakefield – Central
- Wakefield – within the surrounding areas; the Five Towns (Pontefract, Castleford, Knottingley, Featherstone and Normanton), and the towns and villages within the surrounding district

7. Complaints and Terminations

7.1 Complaints

Complaints will be looked at individually to understand the circumstances. The CCG's Medicines Optimisation Team will be the first point of contact to discuss any issues arising from the service specification. wakccg.medsoptwakefield@nhs.net

7.2 Termination of the Contract

The service specification sets out contract termination process:

- Either party can agree in writing to terminate the contract with an agreed date, with a minimum termination notice of 30 days.
- The provider must notify the CCG in writing immediately if any incident occurs which adversely affects delivery of the service e.g., absence, adverse incident, issues with premises and/or the NHS contract etc.
- The CCG will notify the provider in writing if there is failure to meet any contractual obligations allowing the provider to take specified actions to correct the breach in a specified timescale e.g. unable to supply specified medicines
- If the breach is not remedied, the CCG is entitled to terminate the contract immediately by written notice.
- If a pharmacy fails to meet their core contractual obligations as determined by NHSE&I the pharmacy may be removed from the service at the decision of the CCG following advice from NHSE&I.

The CCG has the right to vary the contract giving the provider 30 days' notice in writing.

The contracting pharmacy has the right to refuse the variation and must do so, in writing within 30 days of receipt of the contract variation.

8. Remuneration

Payments are made to the pharmacy contractor as per the following schedule:

- 8 payments of £125 to cover the 2 year period of running of the service (including "In-season and out of season incidents of flu), this is to be claimed quarterly on submission of an invoice (last working day of June, September, December and March).
- The pharmacy will order to maintain the required stock levels on behalf of Wakefield CCG (as per appendix A) and invoice the CCG for reimbursement.
- The pharmacy will be reimbursed for the cost of the antivirals purchased on submission of the claims form (appendix B) with a copy of the invoice.
- Level 1 "Out of Season" – A fee of £7.50 per supply of antiviral medication on

completion of Appendix C following each episode of supply per outbreak and a copy of the delivery receipt. Stock purchased to replace initial funded stocks will be reimbursed by the CCG should they expire. Full details in section 9.

- Level 2 “In season” (supply via FP10) - once dispensed via FP10 the pharmacy will be required to order and replace stock used to ensure maintenance of the correct stock levels as determined in appendix A of this service specification. The dispensing of antivirals will be against FP10s which are reimbursed through the usual route (BSA)

The payment will be made in regard to service provision and submission of invoice in accordance with the current reporting arrangements. Noting the actual costs of acquiring the stock may vary depending on fluctuation in price (therefore invoices of actual costs are requested). The CCG will pay invoices within 30 days of receipt of the invoice in line with NHS standard payment terms.

9. Quality Standards & Key Performance Indicators

Background:

Provision of Antivirals is determined by Department of Health and Social Care according to the state of circulating flu levels in conjunction with Public Health England. Antiviral medicines are Prescription Only Medicines and so these Regulations remain in force at all stages and the commissioning of services that involve supply of antiviral medicines to patients will need to reflect these.

The following describes the 3 levels of flu arrangements at national level and responsible commissioner at these levels:

Level 1 (Out of Season) The CCG will commission primary care professionals to respond to localised outbreaks, assess patients and if indicated recommend the use of antiviral medicines for exposed persons in at risk groups. However, outside of times when the Chief Medical Officer and Chief Pharmaceutical Officer has advised that seasonal influenza is circulating, independent prescribers in community are unable to prescribe antivirals under the General Medical Services regulations for prophylaxis and alternative local commissioning arrangements need to be made. The CCG at this stage is responsible for healthcare assessment of individuals and contacts, drug costs and any professional service arrangements with pharmacies.

Level 2 (In Season) Chief Medical Officer (CMO) Alert can be issued to allow GPs and prescribers working in primary care to prescribe antiviral medicines for the prophylaxis and treatment of influenza at NHS expense. Community pharmacies therefore will cease to operate at Level 1 and respond to presentation of NHS FP10 prescriptions. NHS FP10 prescriptions are submitted to the NHS Business Services Authority (NHSBSA) in the usual way. The CCG no longer requires a Locally Commissioned Service with community pharmacies. However, practices will be signposted to the community pharmacies that are holding antiviral stock in sufficient quantities, should the need arise for rapid access of a large volume of and delivery of antivirals i.e. outbreak in a care home. Individual patients can access any pharmacy they wish or have their prescription sent to their nominated pharmacy.

Level 3 National Flu Line Pandemic Flu Arrangements.

At November 2021 details of how community pharmacies will dispense pandemic stocks and operate at this stage are not known. Information will be released when this Level of activity is required as commissioned and directed by NHS England. The activity in relation to Level 3, should

it be necessary for the CCG to commission this level and has access to pandemic stocks, will be made available to pharmacies through a contract variation to this contract.

Service Specification Summary: Level One

National Prescriber authorisation is not in place for NHS FP10 prescribing.

This level of the Locally Commissioned Service assumes the following:

1. Pharmacies will claim a professional management fee VAT exempt for provision of pharmaceutical advice and supply of antivirals of £125.00 every quarter utilising a paper-based claim for the stock levels as indicated below in the table.
2. Pharmacies procure antiviral supplies via their usual wholesaler

Minimum Pharmacy Stock of Antivirals (Level 1) with professional service fees

Medication	Minimum Pharmacy stock holding	Professional Service Fee VAT Exempt on dispensing
Oseltamivir (Tamiflu®) 75mg capsules (10)	130	£7.50 per item
Oseltamivir (Tamiflu®) 30mg capsules (10)	30	
Oseltamivir (Tamiflu®) 45mg capsules (10)	30	
Oseltamivir (Tamiflu®) 6mg/ml oral suspension sugar free 65ml	13	
Zanamivir (Relenza®) 5mg/ inhalation powder blisters with device	11	

3. Minimum stock holding may be revised depending on prescribing activity, but further fees will be made available reflecting the same arrangements pro rata for additional purchase costs should it be necessary to increase the stock levels above those described above. This decision will be made by CCG Medicines Optimisation Team in conjunction with other health professionals.
4. Stock checks and updates will be requested at a frequency appropriate to the level of activity across CCG by email to the nhs.net email address of the pharmacy contractor to provide the CCG with assurances.
5. Community pharmacies will be responsible for re-procurement of stock to the agreed level.
6. Supply will be made against either a patient specific direction (PSD) or a private prescription. Antivirals that are dispensed against a PSD must be done so under the supervision of a pharmacist.
7. PSDs and private prescriptions are not submitted to the NHS Business Services Authority for reimbursement and professional fees but are retained in the pharmacy.
8. An entry must be made in the private prescription book (which may be electronic), RHS retained in the pharmacy. Upon dispensing an entry is made paper-based invoice to claim a professional service fee according to the details above.

Service Specification Summary: Level Two–NHS FP10 Prescribing in place.

Provision of antivirals is made through national NHS FP10 prescribing for both treatment and prophylaxis and therefore runs alongside “business as usual” arrangements for dispensing NHS FP10 prescriptions. Stock procured for Level 1 provision can be utilised to fulfil NHS FP10 prescription requirements. Stock should continue to be replenished to these minimum levels.

Service Specification Summary: Level Three–National Pandemic Flu Arrangements. N.B. The service is for national stocks only and not for supply under FP10 at this stage.

(The service provider is not beholden to deliver level three provision. Any request to do so will be negotiated as part of a separate service level agreement)

In general, Wakefield CCG undertakes to:

1. Set up site specific access codes/ passwords to facilitate IT functionality and advise of any training reference material if necessary.
2. Provide relevant flu information updates to ALL Community Pharmacies and any additional key information to pharmacies specifically engaged in the antiviral supply at Levels 1,2 or 3.
3. Communicate with pharmacy through wakccg.medsoptwakefield@nhs.net account as a secure means of communication
4. Publicise appropriately the opening hours of community pharmacies providing this service.
5. Recognise that changes to opening hours for community pharmacies require discussion and agreement over and above existing declared contractual opening hours within the community pharmacy contract.
6. Liaise to ensure that effective signposting information to community pharmacies to support the management of patients including advice on supporting patients whose first language is not English is in place.
7. Provide information and support to pharmacies on how to best manage symptomatic patients who present in the pharmacy.
8. Provide advice on infection control measures that are relevant to the pharmacy setting.
9. Reserve the right to withdraw/ re start the service with immediate effect should national/ local guidance change on the use of antivirals in Flu management or Level 2 NHS FP10 based prescribing is either commenced or retired.
10. Provide any required support on drug alerts or drug recalls in relation to these medicines.
11. Provide a framework for the recording of relevant service information for the purposes of audit and claiming for payment with minimal data requirements.

Community Pharmacy undertakes to:

Stock management

1. To store and manage a ‘segregated’ full range of antivirals as agreed with the CCG. Note that this stock can be used to respond to requirements of Level 1 or 2 (NHS FP10) provision
2. Advise the CCG if stock becomes unobtainable with no date expected for delivery whereby the minimum stock levels cannot be kept routinely. This should be communicated by email to wakccg.medsoptwakefield@nhs.net
3. Produce quarterly claims for any antivirals dispensed under Level 1 of this service promptly with maximum grace period of 1 month from provision to date of claim.

Prescribing Guidance

4. Receive latest prescribing guidance and any advice for antiviral prescribing; and advise the CCG on specific situations were requested e.g. Contacting prescribers

should oseltamivir solution be prescribed to anyone over the age of 1 year old for example.

5. Ensure that prescribing information and updates are forwarded to all members of the pharmacy team including any locum pharmacy staff (where practicable). Be familiar with dosing arrangements for prophylaxis and treatment doses including in that of special patient groups.

Clinical Governance

6. Pharmacies should be aware of the need to keep up to date on the current influenza situation via their own reference sources and from the CCG/NHS England. People with symptoms will have been assessed by a healthcare professional using e.g. a HPA algorithm (updated regularly and available at www.hpa.org.uk) since there will be guidance issued at national level.
7. Refer any necessary clinical queries to the prescriber.
8. The CCG requests that all contractors meet or are working towards meeting the Quality Payment Scheme Essential Criteria Checklist Part 1 for COVID-19 to provide assurance all reasonable measures are in place to respond to the COVID-19 pandemic, protecting both themselves and the people using their services. In addition, this allows pharmacies to demonstrate compliance with elements of Health and Safety Legislation
9. Receive and Implement national NHSE/I advice on infection control measures to safely provide this service as updated and where it is applicable to pharmacy premises.
10. Ensure that all pharmacy and medicines counter staff are offered and can access flu vaccination.
11. Ensure that all pharmacy and medicines counter staff are aware of standard operating procedure.
12. Be able to produce business contingency plans within contractual obligations to facilitate continuity of service.
13. All paperwork should be kept as per private prescription requirements referencing information governance principles.
14. Notify Wakefield CCG urgently of any forced closures through wakccg.medsoptwakefield@nhs.net
15. Notify the CCG of any incident reports or concerns relating to antivirals in addition to in house procedures re incident reporting to wakccg.medsoptwakefield@nhs.net

Pharmacy staff

16. Ensure all relevant staff including locums are fully informed of the existence of Pharmacy SOPs/ procedures to ensure continuous service provision.
17. Receive and manage appropriately antiviral stocks of medicines received through either community pharmacy wholesaler distribution network or via other deliveries.
18. Note that no collection of prescription charges will be necessary for the issue of stock at level 1 unless otherwise directed by DHSC.

Dispensing

19. Dispense antivirals from local prescribers or Out of Hours at all times during pharmacy opening hours with reference to clinical protocols provided.
20. Label and record patient details on the pharmacy PMR when making supplies, enter data on a paper system towards claims for professional fees. Template recording document to support claims is provided as Appendix C to this document which should be retained for any clinical or financial audit purposes. Template invoice also provided to forward to Wakefield CCG for any claims.

Antiviral stock list*

Oseltamivir (Tamiflu®) 75mg capsules = 130 boxes @£15.41

Oseltamivir (Tamiflu®) 30mg capsules = 30 boxes @£7.71

Oseltamivir (Tamiflu®) 45mg capsules = 30 boxes @£15.41

Oseltamivir (Tamiflu®) 6mg/ml oral suspension sugar free 65ml = 13 packs @£10.27

Zanamivir (Relenza®) 5mg/ inhalation powder blisters with device = 11 packs @ £16.36

*DM&D: last accessed October 2021. Prices are correct at the time of publication.

Appendix B

Flu Service Audit Form (to be submitted to the CCG quarterly) wakccg.medsoptwakefield@nhs.net

Pharmacy Name:

Pharmacy Address:

Date:

Item	Opening Stock level	Dispensed items – FP10	In season supply replenished Supply replenished?	Dispensed items – Out of Season	Expired stock	balance	Expiry date of stock held
<i>Example – in season Oseltamivir</i>	<i>50x14</i>	<i>2*14</i>	<i>Yes</i>	<i>NA</i>	<i>NA</i>	<i>50*14</i>	<i>48* June 2019 2*June 20</i>
<i>Example - out of season</i>	<i>50*14</i>	<i>Na</i>	<i>NA</i>	<i>2*14</i>	<i>1*14 (expired Jan 19)</i>	<i>47*14</i>	<i>30*March 19 5* June 19 12*Sept 19</i>
Oseltamivir (Tamiflu) 75mg capsules							
Oseltamivir (Tamiflu) 30mg capsules							
Oseltamivir (Tamiflu) 45mg capsules							
Oseltamivir (Tamiflu) 6mg/ml powder for oral suspension							
Zanamivir (Relenza) 5mg/dose inhalation powder							

Community Pharmacy claim form for supply of oseltamivir or zanamavir during out-of-season influenza outbreaks

Date of dispensing	GP Practice of Patient	Item and Quantity Supplied	Cost of Drug Supplied	Dispensing Fee £7.50 – fixed.	Total Cost
<i>e.g. 01/12/2021</i>	<i>The Surgery</i>	<i>Oseltamivir (Tamiflu) 75mg capsules 10 capsules</i>	<i>£15.41</i>	<i>£7.50</i>	<i>£22.91</i>

Antivirals Service claim form

Pharmacy stamp	ODS code F_____	
	Month	Year

I claim payment for the provision of the Antiviral service for the above named pharmacy for the retainer payment of £125 for Quarter (Please indicate quarter)

I confirm that _____ (named pharmacist) has ensured the service specifications have been and will continue to be delivered and all staff and locums have been and will continue to be informed of the service the above named pharmacy provides.

Declaration

I claim payment to the provision of the Antiviral Service for the above named pharmacy. I certify this claim is accurate and the items supplied are in accordance with the Antiviral Service

I declare that the information given on this claim form is true, accurate and complete to the best of my knowledge.

I understand that action may be taken against me if I make an incorrect claim.

I consent to the disclosure of relevant information on this form for the purposes of fraud prevention, detection and investigation.

I understand the CCG must be immediately informed of any personnel changes that may affect the SLA agreement or provision of the service

Please send this form along with all relevant consultation forms to the Medicines Optimisation Team at Wakefield CCG,
wakccg.medsoptwakefield@nhs.net

Signed.....Date.....

For CCG use

Amount payable			
Checked	Approved		
Anti-viral scheme (paid via invoice/BACS)			Date

Appendix E

Date	REASON FOR JOURNEY (indicate here if by public transport – please include receipts)	JOURNEY FROM (The starting point, please include postcodes)	JOURNEY TO (The end point, please include postcodes)	Return Journey? (Y/N)	Total Mileage	Reimbursement £0.56 * total mileage

- **Taxi journeys will be reimbursed upon submission of a receipt/invoice (if a taxi is used the pharmacy must ensure a process is in place to confirm that the delivery has been securely made by the taxi and that patient confidentiality is maintained).**