

<b>Service Specification No.</b>	LCPS5
<b>Service</b>	Locally Commissioned Pharmacy Service – Monitored Dosage System (MDS) Service
<b>Period</b>	24 months
<b>Date of Review</b>	31 March 2024

<b>1. Population Needs</b>
<p><b>1.1 National/Local Context and Evidence Base</b></p> <p>1.1.1 It is estimated that only 50% of people with long term conditions take their medications optimally. Medicines adherence is key to achieving therapeutic goals and improving patient outcomes, whilst non-adherence leads to reduced clinical benefit and generates significant waste<sup>1</sup>.</p> <p>1.1.2 Health and social care professionals have a duty to supply medicines in the safest way and to carefully consider the risks as well as potential benefits in each case. Taking a person-centered approach to medication adherence is necessary to improve medication adherence and therefore to improve patient outcomes.</p> <p>1.1.3 Patients identified as having medicines adherence issues should have a robust individual assessment to identify the best intervention based on their needs and the evidence currently available. This assessment should include a clinical medication review, reasons for nonadherence, medicines suitability, a consideration of appropriate intervention to support the patient and regular follow up.</p> <p>1.1.4 The default should be to supply medicines in original packaging with appropriate adherence aids and consideration should be given to a variety of interventions including non-child resistant closures, medication administration record (MAR) charts, labelling medicines in large fonts, ordering repeat medication for patients, delivery services etc.</p> <p>1.1.5 Provision of a multicompartiment compliance aid (MCA) otherwise known as MDS may be of value for some patients who have been assessed as having practical problems in managing their medicines, enabling them to maintain independent healthy living. However, MDS are not the best intervention for all patients and the evidence-base indicates that due to a lack of patient benefit outcomes, MDS should not automatically be the intervention of choice for all patients.</p> <p>1.1.6 Where a patient assessment indicates an MDS is the intervention of choice, it is important that this is supported with the provision of information, appropriate counselling and follow up for the patient and that the health or social care professional is aware of the legal, professional and practice considerations<sup>2</sup>.</p> <p>1.1.7 Community pharmacies are required as part of their NHS contract to support patients in taking dispensed medications, by making reasonable adjustments for patients with identified needs as per the Equality Act 2010 (formerly Disability Discrimination Act 1995).</p> <p>1.1.8 This service aims to help pharmacies to support independent living in groups of vulnerable people, or those with special needs, who do <b>not</b> fall within the Equality Act 2010 (formerly Disability Discrimination Act 1995) criteria.</p>

1. <https://www.sps.nhs.uk/articles/what-products-or-interventions-are-available-to-aid-medication-adherence/>

2. <https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Support/toolkit/rps-mca-july-2013.pdf>

## 2. Outcomes

### 2.1 NHS Outcomes Framework Domains & Indicators

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

2.2.1 The MDS Service will enable community pharmacies to support patients registered with a GP practice in Wigan Borough who do **not** fall within the Equality Act 2010 (formerly Disability Discrimination Act 1995) criteria where patient assessment indicates an MDS is the intervention of choice and can be used safely by the patient to support independent living.

## 3. Scope

### 3.1 Aims and Objectives of Service

- 3.1.1 To support independent living.
- 3.1.2 To help people manage their medicines safely and appropriately.
- 3.1.3 To reduce wastage of medicines.
- 3.1.4 To improve patient adherence with therapy by:
  - Improving the patient's understanding of their medicines
  - Where possible, simplifying the patient's understanding of the medicines regimen
  - Simplifying the ordering process where appropriate
  - Identifying practical problems the patient faces in taking their medicines and where appropriate providing compliance aids.
  - Providing advice and support to the patient and/or carer, including referral to other health and social care professionals where appropriate.

### 3.2 Service Description

- 3.2.1 The pharmacy will help support independent living in groups of vulnerable people, or those with special needs, who do **not** fall within the Equality Act 2010 (formerly Disability Discrimination Act 1995) criteria.
- 3.2.2 The pharmacy will provide advice, support and assistance to the person with a view to improving the patient's knowledge and use of their drugs and their compliance.
- 3.2.3 The pharmacy will assess the appropriate level or kind of support, if any, required by the person to help them take their medicines as intended, or refer them to another health or social care professional.
- 3.2.4 If support is necessary, the pharmacist will agree with the person or carer the appropriate level or kind of support. Pharmacy support could include compliance charts, non-child resistant closures, medication administration record (MAR) charts, labelling medicines in large fonts and multi-compartment compliance aids (monitored dosage systems). MDS are associated with a higher inherent risk of dispensing errors and therefore increased risk of harm to the patient. The use of MDS must therefore be selectively targeted to patients for whom the usual supply system would have a greater risk of harm. To clarify, MDS must only be used where its use will reduce the overall risk to the patient.

3.2.5 This scheme intends to support an individual to maintain independent living therefore should not be used for patients in nursing homes or residential homes, or for patients who have a carer who can support with medicines administration.

### **General Requirements**

3.2.6 The part of the pharmacy used for provision of the service provides a sufficient level of confidentiality, privacy and safety as required by the patient and/or their carer.

3.2.7 The pharmacy contractor has a duty to ensure that pharmacists and staff involved in the provision of the service have relevant knowledge of compliance support and the Equality Act and are appropriately trained in the operation of the service.

3.2.8 Assessments for this service must be carried out by a pharmacist or a technician registered with the General Pharmaceutical Council.

3.2.9 The pharmacy contractor must have appropriate standard operating procedures in place for the service.

3.2.10 The pharmacy contractor has a duty to ensure that pharmacists and staff involved in the provision of the service are aware of and operate within standard operating procedures.

3.2.11 Pharmacists and technicians providing the service must ensure they have appropriate insurance cover.

3.2.12 The pharmacy contractor must have a vulnerable adults procedure in place.

3.2.13 Pharmacists and technicians must not carry out assessments for this service on family members. If there is another member of staff at the pharmacy able to carry out the assessments then they may provide the service or they must refer them to another pharmacy providing the service.

3.2.14 Pharmacists and technicians providing the service should be trained in systematically assessing patients for compliance support.

3.2.15 To access this service, patients must be referred by their GP using the Compliance Support GP Referral Letter. If patients or their carers approach the pharmacy directly for the service they should be referred to their GP for a referral letter. If a patient does not wish to go to their GP for a referral letter the pharmacy must not refuse to provide support to the patient if they meet Equality Act (formerly DDA) criteria i.e. are disabled. The pharmacy contract requires that pharmacies are required to support patients in taking dispensed medications, by making reasonable adjustments for patients with identified needs as per the Equality Act 2010. The GP referral letter will indicate the supply interval required i.e. should supplies be made monthly (4 x 7 day trays supplied together) or weekly (1 x 7 day tray). Pharmacies may supply GPs with information to inform the decision on frequency of supply e.g. stability of medication in a MDS, problems experienced by patients in the past, but the GP must make this decision.

3.2.16 The pharmacy must then assess the patient to identify the type of support most suitable for the patient and to establish if the patient meets Equality Act 2010 (formerly Disability Discrimination Act 1995) criteria i.e. would be considered to be disabled.

3.2.17 Initial and follow up appointments will normally take place within the community pharmacy, however they could also take place in other environments, such as the person's home, if this is the case the pharmacy must have a lone-workers procedure to ensure the safety of their staff. The assessment should be carried out with the patient and their carer if appropriate.

### 3.2.18 Every initial assessment must include:

- Assessment of the problems being experienced by the patient.
- The patients' current medication routine, establishing what medication the patient is actually taking.
- Identification of the most appropriate support to be provided to the patient by the pharmacy. NB although this service only funds supply of compliance aids it is expected that the pharmacy will only recommend these when required, other support should be considered such as non-child resistant closures, medication administration record (MAR) charts, labelling medicines in large fonts, ordering repeat medication for patients, delivery services etc.
- Assessment of the patient to establish if they meet Equality Act 2010 (formerly Disability Discrimination Act 1995) criteria i.e. are disabled. This step is to enable the pharmacy to claim appropriate payment for the service. This assessment should not affect the pharmacist/technician decision to provide support to the patient.

### 3.2.19 Initial Pharmacy Assessment in Detail:

- **Assessment of the problems being experienced by the patient** – the MDS Scheme Compliance Assessment Form should be completed for all patients requesting this service. It can either be completed in the pharmacy during the assessment or patients/carers can be asked to complete it and return it to the pharmacy prior to the assessment to allow the pharmacist or technician to prepare for the meeting. The pharmacist/technician assessing the patient should obtain as much information from the patient as possible to ensure they are fully aware of the problems being experienced and to enable identification of appropriate solutions. The pharmacist/technician may also want to complete the MDS Pharmacy Assessment Form or any other assessment tool that they feel is suitable in addition to the MDS Scheme Compliance Assessment Form.
- **The patient's current medication routine** – the MDS Scheme Compliance Assessment Form can be used to record this. It is vital that the pharmacy establish which medication the patient is taking and consideration should be made to simplifying the medication regime. If the patient is found to be non-compliant the pharmacist/technician must liaise with the patients GP to establish which medications the GP wants the patient to be re-instated on. For example, if a patient is currently prescribed 3 medications for hypertension but does not take these medications it may be inappropriate to put all 3 medicines into a MDS as this could lead to hypotension.
- **Identification of the most appropriate support for the patient** – the MDS Scheme Compliance Assessment Form will provide information and the pharmacy may also wish to complete the MDS Pharmacy Assessment or an assessment form of their own. In all cases an assessment of whether a compliance aid is required must be carried out. Many patients will not be expected to receive a MDS, as alternative compliance aids will be more appropriate. Appendix 1 lists common compliance problems experienced by patients, and the possible solutions to these problems. Whilst this appendix does not set out directive choices, the Pharmacy contractor is expected to use their professional judgement and this would be expected to be within the scope and spirit of the appendix.

- **Assessment of the patient to establish if they meet Equality Act 2010 (formerly Disability Discrimination Act 1995) criteria** – this assessment must be completed on the DDA Assessment Form. This form must be completed for all patients on the scheme. If this form is not completed the pharmacy cannot claim payment for the service. This form must clearly detail the problems the patient has, any underlying causes, if this is a long-term condition and if the assessor considers the patient to meet DDA criteria i.e. is disabled or does not meet Equality Act 2010 (formerly Disability Discrimination Act 1995) criteria i.e. is not disabled. Under the Equality Act, a person has a disability if he has a physical or mental impairment which has a substantial and long-term (usually lifelong or at least 12 months) adverse effect on his ability to carry out normal day-to-day activities. For example, if a patient is assessed as being confused and they had Alzheimer's disease they would be disabled, if a patient is confused by their medication as they are multiple medications with a variety of frequencies of administration but is otherwise well and does not require any other form of support they would not be disabled. Pharmacy staff providing this service should refer to the Equality Act for further information <https://www.legislation.gov.uk/ukpga/2010/15/contents>. There is also information available from the equality and human rights commission [www.equalityhumanrights.com](http://www.equalityhumanrights.com), the PSNC, the NPA and the PCC amongst others.

3.2.20 If a requirement for a compliance aid is identified this will be provided with training for the patient and/or carer. If MDS equipment is to be supplied it remains the choice of the Pharmacy contractor of which equipment to use.

3.2.21 A follow up appointment should be made to assess whether the support provided has met the patients' needs and to address any problems experienced.

3.2.22 Every patient must be reviewed annually to ensure the support provided is still meeting all the patients' needs and to update the assessment of the patient under the Equality Act. The DDA assessment form must be completed as part of this review. There is no need to obtain a new GP referral letter as part of this review.

3.2.23 If a GP wishes to change the frequency of supply at any time, they must supply the pharmacy with a new GP referral letter.

3.2.24 No claim will be accepted following the decease of a patient after a 28-day period.

3.2.25 The pharmacy must maintain appropriate records to ensure effective ongoing service delivery and audit.

3.2.26 For every new patient using the service the pharmacy must have a GP referral letter, they must complete the Pharmacy MDS Scheme Compliance Assessment form and the DDA Assessment Form.

3.2.27 At every annual review the pharmacy must complete the DDA Assessment Form and ensure that the support provided by the pharmacy continues to meet all the patients' needs.

3.2.28 Completed paperwork for the scheme must be retained securely and in line with the Records Management Code of Practice for Health and Social Care.

3.2.29 Claims for the service should be submitted monthly via the electronic claim platform commissioned by Wigan Borough CCG.

3.2.30 Wigan Borough CCG will provide details of relevant referral points which pharmacy staff can use to signpost clients who require further assistance.

3.2.31 Pharmacy staff 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. All clients' informed consent will be obtained and

documented on the DDA Assessment Form.

### **Population covered**

3.2.32 This service is only available to patients registered with a GP within Wigan Borough CCG and who do **not** meet the eligibility criteria of the Equality Act 2010 (formerly Disability Discrimination Act 1995).

### **3.3 Any acceptance and exclusion criteria and thresholds**

N/A

### **3.5 Interdependence with other services/providers**

3.5.1 GP Practices with Wigan Borough CCG.

## **4. Applicable Service Standards**

### **4.1 Applicable National Standards (eg NICE)**

#### **NICE Quality Standard for Medicines Optimisation (QS120)**

- 4.1.1 Statement 1: People are given the opportunity to be involved in making decisions about their medicines.
- 4.1.2 Statement 2: People who are prescribed medicines are given an explanation on how to identify and report medicines-related patient safety incidents.
- 4.1.3 Statement 3: Local health and social care providers monitor medicines-related patient safety incidents to inform their learning in the use of medicines.
- 4.1.4 Statement 6: Local healthcare providers identify people taking medicines who would benefit from a structured medication review.

#### **NICE Quality Standard for Patient Experience in adult NHS services (QS15)**

- 4.1.5 Statement 1: People using adult NHS services are treated with empathy, dignity and respect.
- 4.1.6 Statement 2: People using adult NHS services understand the roles of healthcare professionals involved in their care and know how to contact them about their ongoing healthcare needs.
- 4.1.7 Statement 3: People using adult NHS services experience coordinated care with clear and accurate information exchange between relevant health and social care professionals.
- 4.1.8 Statement 6: People using adult NHS services are supported in shared decision making.

### **4.2 Applicable standards set out in Guidance and/or issued by a Competent Body (eg Royal Colleges)**

- 4.2.1 General Pharmaceutical Council Standards for registered Pharmacies.
- 4.2.2 General Pharmaceutical Council standards for pharmacy professionals.
- 4.2.3 Royal Pharmaceutical Society Improving Patient Outcomes – The better use of multicompartiment compliance aids.

### **4.3 Applicable Local Standards**

- 4.3.1 The Pharmacy Contractor should review their Standard Operating Procedure for the service when there are any major changes in the law affecting the service or in the event of any dispensing incidents. In the absence of any of these events they will be reviewed every 2 years.

## 5. Applicable Quality Requirements

### 5.1 Quality Indicators

- 5.1.1 Providers should be able to demonstrate that all staff involved in the provision of the service have undertaken CPD relevant to this service.
- 5.1.2 The Pharmacy will permit announced or unannounced visits from Wigan Borough CCG and will co-operate with any locally agreed post payment verification and contract monitoring assessment of the service or service user experience as requested by Wigan Borough CCG.
- 5.1.3 The Community Pharmacy contractor will report any incidents relating to the service to The Commissioner. The Pharmacy team will manage any incidents in line with the requirements of the NHS Contractual Framework for Community Pharmacy.
- 5.1.4 The Pharmacy will effectively manage any complaints using the Community Pharmacy's own internal complaints procedures which must be consistent with the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009, as amended. The Pharmacy team will inform The Commissioner of any complaint relating to the service.

## 6. Payment

### 6.1 Payment Submission

- 6.1.1 Pharmacies are asked to process claims in a timely manner via the electronic claim platform commissioned by Wigan Borough CCG.
- 6.1.2 All claims will need to be submitted by close of play on 27<sup>th</sup> of the month following the month to which the claim relates. Invoices will then be run on the 28<sup>th</sup> of each month. Any claims submitted outside of this period cannot be accepted and payment will not be made.
- 6.1.3 Wigan Borough CCG will make the payments to Pharmacies via an invoice generated by the electronic claim platform commissioned by Wigan Borough CCG.
- 6.1.4 It is the responsibility of the individual Pharmacy Contractor to inform Wigan Borough CCG of any change in ownership or account details which may affect payments for Locally Commissioned Services.
- 6.1.5 Wigan Borough CCG reserves the right to verify claims by, but not limited to, inspecting paper and computer records in accordance with ethical guidelines.

### 6.2 Fees

- 6.2.1 Payments will be made to contractors on a monthly basis.
- 6.2.2 Wigan Borough CCG provides funding for this service for patients living in the community who are self-medicating. NB: However, Wigan Borough CCG does not fund MDS when a patient has a carer at home who can support them with their medication – this includes social services carers or family and friends.
- 6.2.3 **Disabled patient monthly supplies no additional payment** - If a patient is assessed by the contractor as needing MDS under the DDA with no other clinical or pharmaceutical issues, MDS should be provided by the pharmacist (free of charge to the patient) via 28-day scripts. Four weeks supply of MDS should be dispensed at each interval.
- 6.2.4 **Disabled patient requiring weekly supplies** - If a patient is assessed by the contractor as needing MDS under the DDA, but there is a clinical or pharmaceutical issue involved requiring weekly supplies (e.g. the medicines are only suitable for weekly dispensing; the patient is at risk of overdose or medicines regime changing frequently), MDS should be provided by the pharmacist (free of charge to the patient). One week's supply of medication will be dispensed at each interval. The CCG will pay **£10 per patient per month and £7 per patient per month for every patient over 30** for this service.

- 6.2.5 **Non-disabled patient requiring monthly supplies** - If a GP believes that a patient would benefit from an MDS but on assessment by the contractor the patient does not meet the DDA requirements; the CCG will fund this service. The CCG will pay **£10 per patient per month and £7 per patient per month for every patient over 30** for monthly supplies.
- 6.2.6 **Non-disabled patient requiring weekly supplies** - If a GP believes that a patient would benefit from an MDS but on assessment by the contractor the patient does not meet the DDA requirements; the CCG will fund this service. The CCG will pay **£15 per patient per month and £10 per patient per month for over 30** for weekly supplies of MDS.
- 6.2.7 The GP referral letter will state the frequency of supply. Pharmacies can only claim payment for the service indicated by the GP. Therefore if the GP referral indicates monthly supplies but the pharmacy chooses to make weekly supplies the pharmacy must only claim for the monthly service.
- 6.2.8 If a patient believes they need or they want a MDS but the patient does not meet the DDA requirements, and the GP does not believe that the patient will benefit from MDS, then this is outside the scope of the NHS. In this eventuality, the payment must be negotiated between the patient and the community pharmacist.
- 6.2.9 If nursing homes request that patient medicines are to be supplied in MDS as part of their internal policies, then this is a cost falling upon the Care Home provider. Any MDS service will be outside the scope of the NHS and must be negotiated between the nursing home and the community pharmacist.
- 6.2.10 It is a legal requirement that charges equivalent to prescription charges are payable by the patient unless they are exempt from such charges. All patients claiming exemption must be asked to sign the declaration on the recording form. A sample of declarations will be verified at a later date to minimise fraud. Patients who pay prescription charges must be asked to pay a charge at each occasion that a supply is made. A pre-payment certificate should be suggested to any client who might obtain more than 6 items on prescription during a 4-month period.

## **7. Termination of Service and Service Review**

### **7.1 Notice period**

- 7.1.1 Wigan Borough CCG and the contractor should give 3 months' notice of either party's desire to terminate the service.
- 7.1.2 Wigan Borough CCG should give 3 months' notice of any change to the terms of service.
- 7.1.3 Where contractors stop providing this service, they should inform the Medicines Management Team immediately (01942 482838 / 07810181043) and endeavour to re-engage in the service as soon as possible.
- 7.1.4 The service will be reviewed in 24 months
- 7.1.5 Next review: March 2024.



## Appendix 1 Common compliance problems experienced by patients

Problem	Cause	Possible Solution
Obtaining medicines from Pharmacy	<ul style="list-style-type: none"> <li>Poor mobility/housebound</li> </ul>	<ul style="list-style-type: none"> <li>Community Pharmacy delivery service</li> <li>Input from carer</li> </ul>
Accessing medication from packaging	<ul style="list-style-type: none"> <li>Poor dexterity e.g. arthritic hands</li> <li>Poor sight</li> <li>Unsuitable container</li> </ul>	<ul style="list-style-type: none"> <li>Change container e.g. plain/winged tops, non-crc, pop out tablets</li> <li>Provide aids to open container</li> <li>Provide device to aid removal</li> <li>Input from carer</li> </ul>
Reading label/identifying medicine	<ul style="list-style-type: none"> <li>Poor sight</li> </ul>	<ul style="list-style-type: none"> <li>Large print labels</li> <li>Braille labels</li> <li>Coloured/coded labels</li> </ul>
Swallowing medication	<ul style="list-style-type: none"> <li>Unsuitable formulation</li> <li>Swallowing problems e.g. after stroke</li> </ul>	<ul style="list-style-type: none"> <li>Change formulation e.g. soluble or liquid.</li> <li>Crush/break tablets (if medication is suitable)</li> </ul>
Administering liquids	<ul style="list-style-type: none"> <li>Poor dexterity</li> </ul>	<ul style="list-style-type: none"> <li>Spoon/measure/cup/oral syringe</li> </ul>
Applying topical preparations	<ul style="list-style-type: none"> <li>Poor mobility</li> </ul>	<ul style="list-style-type: none"> <li>Input from carer</li> <li>Lotion applicator</li> </ul>
Using inhalers	<ul style="list-style-type: none"> <li>Poor dexterity</li> <li>Unsuitable device</li> <li>Poor technique</li> </ul>	<ul style="list-style-type: none"> <li>Change device</li> <li>Haleraid</li> <li>Advice on technique</li> <li>Use spacer</li> </ul>
Administering eye-drops	<ul style="list-style-type: none"> <li>Poor dexterity</li> <li>Poor technique</li> </ul>	<ul style="list-style-type: none"> <li>Advice on technique</li> <li>Eye drop administration aid</li> </ul>
Forgetfulness	<ul style="list-style-type: none"> <li>Poor memory</li> <li>Complicated regime</li> <li>Confusion over medicines</li> </ul>	<ul style="list-style-type: none"> <li>Simplify regime</li> <li>Ensure understanding</li> <li>Reduce number of medicines to a minimum</li> <li>Link to "cues" (meal times, daily rituals)</li> <li>Reminder chart</li> <li>Tablet organiser/MDS</li> </ul>
Intentional non-compliance	<ul style="list-style-type: none"> <li>Confusion/misunderstanding/misconception</li> <li>Patient beliefs</li> </ul>	<ul style="list-style-type: none"> <li>Simplify regime</li> <li>Promote understanding and dispel misconceptions</li> <li>Accept informed dissent</li> <li>Perform Medicines Use Review</li> </ul>