Leicester, Leicestershire and Rutland
Integrated Care Board

LLR Medicines Management requirements for Independent Sector Healthcare Providers

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LLR Medicines Management for Independent Sector Healthcare Providers

1.0 General provisions

Leicester, Leicestershire and Rutland LLR (ICB) are required to ensure that the services it provides are safe, effective and fit for purpose.

1.1 Non-Commissioned Services

For non-commissioned activity (NCA), obligations under the Review and Contract Management provisions in GC8-9 [1] apply equally in NCA relationships as in the provider's relationship with its host ICB.

Oversight of quality of the service will be managed by the host provider. However, where serious concerns become apparent regarding the quality of an NCA provider's services, LLR will seek assurance and resolution from the host ICB, escalated in accordance with National Guidance on Quality Risk Response and Escalation in Integrated Care Systems or the Care Quality Commission will be alerted. [2-3]

1.2 Commissioned Services

Where commissioned services require the supply, storage or administration of medicines, all providers are required to assure the commissioner that their services utilise medicines in a safe, effective and cost-effective manner. LLR ICB has a medicines assurance framework in place that outlines the requirements that commissioned providers need to fulfil to provide such assurance.

2.0 Medicine Assurance Framework for Commissioned IHP Services

LLR ICB requires all providers to make an annual assurance statement through completion of the Medicines Assurance Framework. Providers are also required to complete and submit a bi-annual medicines safety report.

The Medicines Assurance Framework is a contractual requirement and forms part of the schedules of the Standard NHS Contract. Submissions will be reviewed annually by the ICB Medicines Governance team (as part of the annual Quality Assurance return) and any resultant recommendations passed through to the ICB Contract Managers for notification to the provider.

2.2 Specific requirements relating to medicines

The requirements relating to medicines apply to any provider that carries out any of the following activities:

a. Have in-house clinical pharmacy services
b. Store medicines for administration or supply to patients
c. Employ medical prescribers
d. Employ non-medical prescribers
e. Prescribe medicines or supply/administer medicines under a Patient Specific Direction (PSD)
f. Supply or administer medicines under a Patient Group Direction (PGD)
g. Prescribe/store/supply/administer controlled drugs
h. Advise or support patients on the use of medicines.

The following requirements apply to all providers unless they do not apply to their service specification:

2.22 Controlled Drugs

a. The provider has a named accountable officer for controlled drugs who reports into the provider board and is registered with the CQC as an accountable officer where required.

b. The accountable officer is part of the local Controlled Drugs Local Intelligence Network

c. The provider has completed the CQC Self-assessment tool within the previous 12 months and has an action plan in place for resolving any issues rated as amber or red and this action plan is available to commissioners for assurance purposes.

d. The provider current controlled drugs policy in place and can evidence implementation throughout the organisation

2.23 Medicines Governance

e. The provider has an up-to-date Medicines Policy and can evidence implementation throughout the organisation.

f. The provider has, where appropriate, reviewed its clinical pharmacy services within the previous 12 months to ensure that they comply with a relevant set of standards. Examples of relevant standards would include the RPS Professional Standards for Hospital Pharmacy Services.

g. The provider has an up-to-date procedure for identifying medicines that may be designated “high risk” in terms of their raised potential for harm in normal use and has procedures in place to mitigate the risk of harm to patients. This also applies to medicines which may not be regarded as high risk in and of themselves but are used in procedures which are inherently high risk.

h. The provider has a dedicated Medicines Committee or organisational meeting which reviews compliance with current regulations, approves up to date processes / policies and is the focal point for all issues related to medicines. The organisation will be able to demonstrate the governance structures that link the committee to the Trust/Executive board and have clear processes for escalation of issues onto the board assurance framework or equivalent.

2.24 Local and national guidance

The provider uses the **LLR Area Prescribing Committee Formulary** when prescribing/supplying/administering medicines to patients registered with a GP in LLR ICB.

The provider reviews and implements the appropriate requirements and standards outlined in NICE Guidelines / other guidance related to medicines including, but not limited to:

- LLR Medicines Code [4]
- NICE NG15: Antimicrobial Stewardship
- Public Health England antimicrobial validation protocol (where applicable)
- NICE CG183: Drug allergy: diagnosis and management
- NICE NG5: Medicines optimisation
- NICE NG197: Shared decision making
- NICE NG56: Multimorbidity
- NICE CG76: Medicines Adherence
- NICE MPG2: Patient Group Directions
- NICE SC1: Managing Medicines in Care Homes

The provider has processes in place to ensure that patients who meet the requirements for treatment under a NICE medicines Technology Appraisal (TA) have access to the medicines.

2.25 The provider has appropriate procedures in place to seek funding for patients requiring medicines that are:

- not covered by the PbR Tariff **or**
- not covered by a NICE TA **or**
- not in the local IMOC formulary **or**
- not included in a local commissioning policy

2.26 The provider is compliant with the national guidance on ‘medicines of low clinical value’ and ‘over the counter medicines’ or is partially compliant with an action plan in place to address and gaps.

3.0 Incidents and alerts involving medicines

The provider has a standard operating procedure (or equivalent) for the investigation, reporting and severity classification of incidents involving medicines.

The provider has a designated Medication Safety Officer and a dedicated committee / sub-committee that has overall responsibility for medication safety issues. The provider will be able to demonstrate the governance structures that link the committee to the Trust Medicines Committee and /or Trust board and have clear processes for escalation of issues onto the board assurance framework or equivalent.

The provider has a standard operating procedure (or equivalent) for responding to medicine/medical device alerts and recalls, such as those disseminated through the Central Alerting System (CAS) or by bodies with regulatory powers for medicines governance.

The provider has an up to date (last 12 months) risk assessment of its Electronic Prescribing and/or administration Systems that identifies potential risks to patient safety and the plan in place to reduce harm to patients as a result.

The provider has a fully functioning electronic patient medication record system for recording clinical information and prescriptions.

4.0 Prescribing arrangements under an NHS Contract for IHPs

For commissioned and non-commissioned activity, where the service specification permits prescribing, LLR will arrange for the provider to be given access to NHS prescriptions via the NHS Business Services Authority. The provider will need to note the following points:

4.1 NHS Prescriptions

a. The provider will be permitted to prescribe using standard form FP10 prescriptions with transfer via the electronic prescription service being the preferred default.

b. For the purposes of cost management, the provider will be designated an Independent Sector Healthcare Provider (ISHP).

c. Details of ISHP arrangements can be found on the NHS Business Services Authority website (Independent sector healthcare providers | NHSBSA). [5]

d. The commissioner will only permit use of FP10 prescriptions in services where the charges for prescribing are passed back to the provider. For the avoidance of doubt, the commissioner will not permit FP10 prescribing

reimbursement to be charged directly to the commissioners NHS cost centres.

e. The ISHP is responsible for all administration related to prescription cost centre management, medical prescriber allocation, spurious code allocations and non-medical prescriber (NMP) allocation.

f. The ISHP is designated a parent organisation for the purposes of NHS prescription cost management. The ISHP will be responsible for setting up an appropriate set of cost centres and have a system in place with surrounding governance to allow it to be able to accurately differentiate prescribing for patients of LLR ICB from those of other commissioners.

g. Where a prescriber is to be added to the ISHP cost centres, the ISHP retains accountability for verifying that the prescriber is appropriately registered with a UK regulator and is competent to prescribe.

h. Where a medical prescriber is also a general practitioner in any part of the country, the ISHP will ensure that an appropriate spurious prescriber code is obtained and allocated to the medical prescriber before the prescriber is issued with prescriptions.

i. Where an NMP is employed as a prescriber, the ISHP will ensure that the NMP is registered to an ISHP cost centre prior to issuing of prescriptions.

j. Stationery costs associated with prescription pads will be borne by the provider.

k. Pharmacy remuneration fees for dispensing prescriptions will be borne by the provider.

l. LLR ICB will not reimburse the provider or its sub-contractors for any additional costs associated with delivery of medicines to patients or provision of auxiliary aids for people eligible under the Equality Act 2010.

m. Where injectable medicines are prescribed, sharps bins for injections should be prescribed on FP10.

2. Private prescriptions

a. It is recognised that some providers may have existing processes in place or prior arrangements made with other commissioners

b. LLR ICB will permit (i.e. will reimburse) medications to be prescribed on a private prescription basis if all the following criteria are met.

i. An exceptional circumstance has been identified that prevents the provider from utilising the NHS prescription services.

ii. The exceptional circumstance has been agreed with the commissioner.

iii. The provider has agreed to charge the commissioner at a rate equivalent to that which would be charged if the prescription was issued under an FP10.

c. Where private prescriptions are issued, all prescribers are appropriately registered to prescribe controlled drugs on private prescriptions, irrespective of whether they prescribe or intend to prescribe controlled drugs, if the service routinely prescribes controlled drugs.

d. Guidance on prescribing controlled drugs can be found at NHS Prescriptions Factsheet (V2) (nhsbsa.nhs.uk)

3. General provisions on reimbursement

a. Providers should refer to the NHS Who Pays Guidance to determine where the ICB is the responsible commissioner for their NHS care before invoicing the ICB for non-contracted activity. [6]

b. Where there are several appropriate options, the provider must consider the use of the most cost-effective agent as a priority.

c. LLR ICB will pay appropriate costs as determined by the NHSBSA Drug Tariff.

d. Unless it has been agreed with commissioned services and the ICB that prescribing costs are the responsibility of the Provider as outlined in the service specification, LLR ICB will reimburse the provider for medication expenses incurred by the provider, subject to an invoice being raised containing all the data specification requirements below.

e. LLR ICB will not reimburse costs associated with the following:

i. Provision of a medicine, devices, or appliances associated with medicines that are not listed on the LLR Formulary as a currently approved medicine (in the green, amber or red classification**).**

ii. Medicines that are assigned an LLR RED traffic light or listed as part of national policy as less suitable for prescribing in primary care if the expectation is that primary care clinicians will be expected to continue prescribing.

iii. Provision of medicines with a NICE TA but which is still classified as Do Not Prescribe (DNP) as per the LLR Traffic Light System or does not meet local prescribing criteria.

iv. Medicines or appliances that have been prescribed which fall outside the commissioned service

v. Medicines that are included in part XVIIIB, part XVIIIC or XVIIID of the drug tariff

vi. Costs that are incurred through high volume prescribing (specifically the Expensive Prescription Fee)

vii. Prescriptions for appliances that are not included in Part IX of the Drug Tariff

viii. Medicines that are used outside of their licence as specified in the Summary of Product Characteristics

ix. Medicines that are used where national guidance does not support their use. Providers should normally seek prior approval for such use via the ICB individual funding requests process

x. Medicines that have been prescribed for patients not registered with a LLR general practice

xi. Patients who do not meet local eligibility criteria for treatment

xii. Value Added Tax

5. Data requirements for reimbursement of medicines costs

LLR ICB is committed to reimbursing providers of services in a prompt and accurate manner. The ICB reserves the right to undertake post payment verification of all medicines costs and to deduct ineligible payments from future invoice payments.

Post payment verification requires a minimum dataset which is considered a mandatory minimum standard for this service specification. The provider is required, for all invoices, to provide the following dataset. Note that although not required for invoicing, all prescribing records must be able to be linked back to the patients NHS number.

a) The minimum data specification for invoicing:
b) The date of prescription issue.

c) The provider's unique identifier for the patient noting that this must be consistent throughout the patient's registration with the provider. The provider's unique identifier must not be the patients NHS number.
d) The patient's basic demographic information (date of birth, sex).
e) The patient's general practice ODS code and referring clinician details.
f) The presentation name of the medicine prescribed (e.g. paracetamol 500mg tablets).
g) The dose prescribed (noting that this must specific the number of doses to be taken and the frequency).
h) The quantity prescribed.
i) The cost of the prescription being charged to the commissioner.

The minimum dataset is to be provided at the time of invoicing for medication costs. The dataset will be provided via a secure route as advised by the ICB contracts team.

5.1 Invoice frequency

The frequency of invoicing should be monthly.

5.2 Invoice monitoring

LLR ICB will monitor the use of the RTC prescribing codes, and if discrepancies arise, these will be managed assertively. Should we be unable to resolve adequately, concerns will be escalated to the host ICB. Repeated improper use of the code, or failure to engage with commissioners to address any highlighted issues, will lead to withdrawal of the code and the contract deemed not qualifying, unless an alternative mechanism to enable NHS prescribing is agreed by all parties.

6.0 Shared care with NHS General Practice

Shared care is a provision that allows specialist clinicians in an NHS provider to request the co-operation of the patients General Practitioner in sharing the ongoing care of a patient, once an initial treatment plan has been implemented and the patient is stable to be handed over. All providers considering shared care as an option should note the following requirements:

a. Shared care is not a mandatory part of the general medical services contract and GPs can only be invited to participate. A GP is under no obligation to participate in shared care and is not required to provide an explanation to the requester if they do not

b. The patient must consent to be a party to a shared care agreement.

c. Shared care is not a mechanism where one prescriber can delegate prescribing to another. Patients must not be left with an expectation (implicit or explicit) that their

GP will pick up prescribing responsibilities. The provider must be explicit with the patient that ongoing prescribing will remain with the provider if the GP is unwilling to participate.

d. The provider must take particular care not to damage the GP-patient relationship through implying that a GP will take on shared care prescribing without the express agreement of the GP'

e. Shared care is covered by professional standards that can be found here: Shared care - professional standards - GMC (gmc-uk.org).

f. All prescribers are expected to pay due consideration to the professional guidance before considering shared care.

g. General practitioners are in receipt of generic shared care advice from the ICB that reminds them of their obligations to consider wider factors when responding to a request from a non-NHS organisation.

h. Where a GP declines to participate in shared care:

- The ongoing prescribing responsibility remains with the provider
- The provider must maintain an up-to-date clinical business continuity plan to cover situations where the provider is unable to operate or when the contract is under notice. The service provider is required to maintain arrangements for an enduring duty of care if transfer to another NHS service is not achievable within the timeframes of the contract notice period.
- The provider retains an obligation to notify the GP of initiation and changes to therapies throughout the time the patient is under the provider's care.
- The provider checks the patient's medication profile on the national summary care record before each prescription.

i. The provider must procure diagnostic services as required to ensure that medicines are monitored in line with Specialist Pharmacy Services medicines monitoring or, in the absence of SPS guidance, in line with the summary of product characteristics.

j. Where a GP accepts an invitation to participate, the provider must supply an approved shared care agreement. Locally ratified shared care agreements are available on the LLR ICB website. The provider may elect to use nationally approved (but unaltered) shared care agreement as made available by NHS England.

k. Shared care agreements require specific consent of all parties and consent must be obtained prior to transfer of care

7.0 Specific service requirements

7.1 Attention deficit hyperactivity disorder (ADHD)

a. The provider must base their clinical service model upon NICE quality standards described in NICE NG87: Attention deficit hyperactivity disorder: diagnosis and management. [7]

b. Providers must demonstrate that their service model and outcomes reflect the NICE guidance that non-pharmacological interventions are considered before and in addition to considering medicines.

c. Medicines must be prescribed in line with the NICE guidance and the LLR Formulary with due reference to diagnostic testing required prior to medicines commencing

d. Providers should be aware of the NICE guidance not to use medicines not listed in the guidance and comply with LLR Formulary recommendations.

e. Providers should be aware of the LLR Shared Care Agreement for ADHD medicines for Adults and Children. [8]

7.2 Overweight and Obesity Management

a. The provider must base their clinical service model upon NICE quality standards described in NICE NG 246 Overweight and obesity management.[9]

b. Providers must demonstrate that their service model and outcomes reflect the NICE guidance that non-pharmacological interventions are considered before and in addition to considering medicines.

c. Medicines must be prescribed in line with the NICE guidance and the LLR Formulary with due reference to diagnostic testing required prior to medicines commencing.

d. Providers should be aware of the NICE guidance not to use medicines not listed in the guidance and comply with LLR Formulary recommendations.

e. Providers must not accept referral of patients who do not meet the LLR eligibility criteria for treatment under this pathway. [10]

Section 8 References

1. NHS Standard Contract https://www.england.nhs.uk/wp-content/uploads/2024/02/07-NHS-Standard-Contract-2024-to-2025-General-Conditions-shorter-form-February-2024.pdf.

2. Frequently asked questions about non-contract activity (NCA) 24-09-24. NHS England » 2025/26 NHS Standard Contract

3. NHS England » National Guidance on Quality Risk Response and Escalation in Integrated Care Systems.

4. LLR Medicines Code

5. Independent sector healthcare providers | NHSBSA

6. NHS England » Who Pays?

7. Overview | Attention deficit hyperactivity disorder: diagnosis and management | Guidance | NICE.

8. Traffic Lights - Leicester, Leicestershire and Rutland Area Prescribing Committee

9. Overview | Overweight and obesity management | Guidance | NICE

10. LLRAPC Position Statement for Treatment of Obesity Link