

Local Enhanced Service Specification:

Shared Care of Medicines

Service Specification No.	
Service	High Risk Drugs – Shared Care
Commissioner Lead	Lancashire and South Cumbria ICB
Provider Lead	GP Practices in Lancashire and South Cumbria
Period	1 st May 2025 – 31 st March 2026
Date of Review	To be reviewed annually
Last Updated	16 th May 2025

1. Population Needs and Background

1.1 National/local context and evidence base

All practices are expected to provide essential and those additional services they are contracted to provide to all their patients. This enhanced service specification is for the monitoring of several secondary care initiated amber drugs that require monitoring at three/six monthly intervals or more frequently. The specification of this service is designed to cover the enhanced aspects of clinical care of the patient all of which are beyond the scope of essential services. No part of the specification by commission, omission or implication defines or redefines essential or additional services.

The treatment of several diseases within the fields of medicine, are increasingly reliant on drugs that, while clinically effective, need regular blood and other monitoring. This is due to the potentially serious side-effects that these drugs can potentially cause. It has been shown that the number of side-effects can be reduced significantly if this monitoring is carried out in a well-organised way, close to the patient's home. Medicines that have been designated with an Amber traffic light are considered suitable for a GP to monitor within their practice **once the drug has been initiated and stabilised within secondary care.**

In 2018, the NHS England Primary Care Delivery: Policy & Strategy, Operations & Information Directorate in partnership with BMA, RCGP, RCN and NAPP issued guidance entitled Responsibility for prescribing between Primary & Secondary/Tertiary Care. This defined shared care as: "Shared care agreements are a specific approach to the seamless prescribing and monitoring of medicines which enables patients to receive care in an integrated and convenient manner. Shared care is a particular form of the transfer of clinical responsibility from a hospital or specialist service to general practice in which prescribing by the GP, or other primary care prescriber, is supported by a shared care agreement."

2. Scope & Service Standards

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 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

- To ensure care is delivered in a timely manner and in a convenient location closer to the patient's home.
- Improved patient experience
- Reduced need for onward referral
- Improved monitoring of patients on high-risk drugs resulting in improved patient safety

3. Scope & Service Standards

3.1 Aims and objectives of service

This service is designated to remunerate practices for additional work involved in monitoring amber secondary care-initiated drugs within the GP practice that have been stabilised within secondary care and that require frequent monitoring at various intervals.

Service Aims:

- Ensure patient convenience, whilst remaining clinically safe.
- Ensure patients receive the necessary and appropriate monitoring at the right time.
- Clinicians involved are confident in accepting the legal and clinical responsibility associated with the prescribing of these medicines.
- Therapy should only be stated for recognised indications for specified lengths of time.
- Maintenance of patients first stabilised in the secondary care setting should be properly controlled.
- Monitoring of patient's therapy is managed through their GP practice, standardising the provision and use of blood test monitoring.
- The need for continuation of therapy is reviewed regularly by the specialist.
- The therapy is discontinued when appropriate.
- The use of resources by the National Health Service is efficient.

3.2 Service Description/Care Pathway

The service will provide near patient testing associated with the prescribing of medicines designated as Amber level 2 (with shared care and enhanced service) or considered to be high risk and requiring more frequent monitoring than on an annual basis.

This service includes drugs for rheumatology patients commenced on DMARDS (Disease Modifying Antirheumatic Drugs) plus medicines designated in Lancashire and South Cumbria as requiring intensive monitoring.

The provider must ensure that all newly diagnosed/treated patients (and/or their carers, where appropriate) receive appropriate education and advice on the management and prevention of secondary complications of their condition. This should include written information, where appropriate.

The provider must ensure that all patients (and/or their carers and support staff, where appropriate) are informed of how to access appropriate and relevant information.

The provider must ensure that all patients have an individual management plan which gives the reason for the treatment, the planned duration, the monitoring timetable and, if appropriate, the therapeutic range to be obtained. This information should all be included within the clinical record.

3.3 Population covered

The service is to be provided for all eligible residents of that are registered with a GP in Lancashire and South Cumbria ICS.

3.4 Any acceptance and exclusion criteria and thresholds

All patients must be registered with a GP Practice in Lancashire and South Cumbria, those that are not will be excluded from this service.

This service is intended to cover NHS shared care (including with approved right to choose providers). However, where a practice has considered the criteria in the Local Guidelines for Good Prescribing in Primary care and feel sufficiently assured to choose to agree shared care with a private provider for medications covered by the shared care agreements, this specification applies.

3.5 Interdependence with other services/providers

Staff involved with the provision of this service must work together with other professionals where appropriate. The provider should refer patients to other appropriate services and to relevant support agencies using locally agreed guidelines.

Links to the current, agreed clinical shared care guidance can be found on the LSCMMG site at: <http://www.lancashireandsouthcumbriaformulary.nhs.uk/>

Additional drugs may be introduced to the above list within the contract year if approved by LSCMMG. Where this occurs, practices will be fully informed and funded according to the agreed monitoring frequency at the agreed rates below.

Shared care protocols

Practices should ensure there is a completed and signed Shared Care Agreement attached to the patient notes.

Practices must adhere to the ICB agreed Shared Care Protocols for each drug – on <http://www.lancashireandsouthcumbriaformulary.nhs.uk/>.

Occasionally tertiary services may ask practices to use shared care protocols agreed in their geography. The Northwest is aiming to align these to reduce or eliminate any duplication or contradiction.

This service specification will fund out of area shared care if agreed by the medicines optimisation team.

A register

Practices should be able to produce and maintain an up-to-date register for each of the secondary care-initiated drugs monitored via this service. Each register should include the patients name, date of birth and the indication and duration of treatment and last hospital appointment.

Practices should have robust systems in place to ensure systematic call and recall of all patients on the register is taking place for appropriate monitoring to occur. If practices do not provide this service, the practice must make appropriate arrangements to ensure patients are monitored safely through an alternative provider.

Although systems such as Eclipse RADAR can support practices through safety netting e.g. identifying patients at an increased risk of harm due to a failure in the call and recall system or failure to act on abnormal results, they are not a substitute or intended as an alternative to a robust call and re-call system.

Practices must maintain adequate records of the service provided, incorporating all known information relating to any significant events.

3.6 Equipment / Premises

The provider must ensure any equipment used has been quality assured and that the service is delivered from premises that meet the current regulatory standards.

3.7 Governance and Safety

Practices must ensure that monitoring is accurate and up to date before a prescription is issued. The expectation is that monitoring and prescribing will be undertaken by the same provider.

3.8 Audit, Record Keeping and Reporting

The provider must be able to produce an up-to-date register of all patients receiving a medicine as outlined in Appendix A; including patient name, date of birth and the initiation and duration of treatment, including the last hospital appointment.

The provider must maintain adequate records of the service provided including all

regular monitoring, dates of attendance, issues arising from treatment and incorporating all known information relating to any significant events e.g., hospital admissions, death of which the practice has been notified.

Patients' records should be assigned the relevant SNOMED Code to allow relevant audits to be conducted. Patients who are prescribed any shared care drug as per LSCMMG (as the list may change depending on LSCMMG decisions) and who receive the monitoring and/or adjustment of therapy by the practice should be SNOMED coded differently to those patients who receive their monitoring and adjustment by Secondary/Tertiary Care:

- Where patients are receiving monitoring with or without adjustment of therapy by the practice and NOT under this local enhanced service the following SNOMED Code should be used Eg. DOACs:
High Risk Drug Monitoring – Primary Care SNOMED 205791000000105
- Where patients are receiving monitoring with or without adjustment of therapy by Secondary/Tertiary care thus payment is not being claimed under this local enhanced service the following SNOMED Code should be used:
High Risk Drug Monitoring – Secondary Care SNOMED 205811000000106
- Where patients are receiving monitoring with adjustment of therapy by the practice and payment is being claimed under this local enhanced service the following SNOMED Code should be used:
High Risk Drug Monitoring – Shared Care SNOMED 20581010000109
Payment will be made based on this SNOMED code
- Where treatment is stopped the following SNOMED Code should be used:
High Risk Drug Treatment Stopped - SNOMED 170912005

The provider must ensure that a systematic call and recall of patients on the Practice register is taking place.

All providers of NHS commissioned care should use the latest NHS Information Governance Toolkit to assist in implementation and assessment of compliance with policy and legal requirements.

Full records of all procedures, screening and tests should be maintained in such a way that aggregated data and details of individual patients are readily accessible. Practices should regularly audit and peer review outcomes.

Practices must ensure that details of the patient's monitoring are included in his or her lifelong record. If the patient is not registered with the Practice, then the Practice must send this information to the patient's registered Practice for inclusion in the patient notes.

3.9 Inclusion and Exclusion Criteria

Inclusion: All amber shared care drugs that **require bloods** and other monitoring/ investigations as part of the recommended monitoring more frequently than per annum and above 'usual care'.

Exclusion: Any amber drugs that do not require shared care or bloods as part of the

recommended monitoring. Recommended annual assessment should form part of the standard clinical annual review process.

4. Finance

4.1 Finance

Payment should only be claimed for those patients who receive near patient testing and monitoring by the practice, including taking clinically appropriate action in response to results and patient response.

Patients who receive their monitoring of therapy and subsequent adjustments in secondary/tertiary care should be SNOMED coded in a different manner and payment should not be claimed.

The provider will receive payments based on the intensity of testing required.

- For drugs that require up to and including 3 monthly tests an annual fee of £120 per patient per year
- For drugs that require up to and including 6 monthly tests an annual fee of £60 per patient per year will be paid.
- For drugs that require 12 monthly testing an annual fee of £30 per patient per year will be paid.

For patients on two or more medications listed within this service specification practices should claim for monitoring one patient only unless the monitoring requirements of each drug is significantly different from the other.

Practices are required to submit claims in accordance with the monitoring requirements and respective SNOMED codes and these should be submitted on a quarterly basis using the claim form provided.

All activity should be recorded using the appropriate READ/SNOMED codes. All details regarding data quality and submission of data can be found in the supporting Technical Guidance Document.

Phlebotomy is commissioned separately and is outside the scope of this service specification.

Practices will be required to validate their patient numbers at the end of each reporting period (quarterly or 6-monthly as per monitoring requirements below) using the MLCSU Data Quality searches available on Enterprise Searches and Reporting (ES &R).

Practices will receive payments at the end of each reporting period (quarterly, 6-monthly or 12 monthly as per monitoring requirements above) according to the number of patients and frequency of monitoring requirements.

Validation confirmation must be submitted to:

[Monitoring of High Risk Drugs Data Validation Submission](#) by 10th of each quarter (July, October, January, April) for processing. Delayed validation confirmation may result in payments being delayed or suspended.

4.2 Drugs included and costs per patient per annum

The following payments can be claimed at the appropriate monitoring frequency as defined in the shared care guideline for each drug/indication. Drug list updated by LSCMMG. See <http://www.lancashireandsouthcumbriaformulary.nhs.uk/> for monitoring requirements and indications.

Drugs requiring up to and including Quarterly monitoring	VALUE/ £
Azathioprine	120
Sulfasalazine	120
Ciclosporin	120
Leflunomide	120
Lithium	120
Mercaptopurine	120
Methotrexate	120
Mycophenolate	120
Penicillamine	120
Sodium aurothiomalate	120
Hydroxycarbamide	120
Dapsone	120
Drugs requiring up to and including 6 monthly monitoring	VALUE/ £
Apomorphine	60
Amiodarone	60
Denosumab	60
Dronedarone	60
ADHD drugs <ul style="list-style-type: none"> • Atomoxetine • Dexamfetamine • Guanfacine • Lisdexamfetamine • Methylphenidate 	60
Drugs requiring up to and including 12 monthly monitoring	VALUE/£
Antipsychotics	30
Testosterone	30
Riluzole	30

Any additional drugs agreed in year will be added to this list based on the appropriate frequency of monitoring.

4.3 Fraud Policy

In the event of suspected fraud or other illegality being uncovered at any stage the ICB will implement the ICB Fraud Policy and will investigate.

Information supporting reported activity and monitoring information must be made available to the ICB or its representatives upon request. Failure to provide this information, or the provision of incomplete or inaccurate information, may result in suspension of payments or clawback, as well as further investigation by the ICB and its representatives.

5. Applicable Service Standards

5.1 Applicable national standards (e.g. NICE)

The delivery of the commissioned service is underpinned by the appropriate standards, including but not limited to:

- *Dept. of Health EL(91)127 "Responsibility for prescribing between Hospitals and GPs"*
- Care Quality Commission Standards
- Code of Practice for the NHS on the prevention and control of healthcare associated infections and related guidance
- Relevant safeguarding standards.

5.2 The service provider is required to adhere to all current infection prevention guidance including the Health and Social Care Act 2012 and NICE Guidance CG139 or relevant guidance which supersedes these detailed.

5.3 Applicable standards set out in Guidance and/or issued by a competent body

5.4 Applicable local standards

Prescribing by a Primary Care prescriber of an Amber level 2 (with shared care and enhanced service) should normally be carried out in accordance with the guidance provided in the LSCMMG Monitoring Guidelines and/or the shared care protocol (where available) for that drug. Current shared care protocols are updated regularly. The most up to date version should be used and can be found at:

<http://www.lancashireandsouthcumbriaformulary.nhs.uk/>

These guidelines provide best practice guidance for monitoring these drugs, with information accrued from a variety of sources.

Adherence to the guidelines will not ensure a successful outcome in every case. The ultimate judgement regarding a particular clinical result must be made by the clinician considering the clinical data presented by the patient and the diagnostic and treatment options available.

A provider may be accepted for the provision of the service if it has a partner, employee or sub-contractor who has the necessary skills and experience to undertake the required patient monitoring to the standards of this specification. Providers undertaking this service will be required to demonstrate a continuing

sustained level of activity, conduct regular audits, be appraised on what they do and take part in necessary supportive activities.

The provider is required to maintain evidence of continuing professional development in relation to this service specification. This may be produced as evidence for re-accreditation. Clinical updates/training could include supervised practice, liaison/clinical audit sessions and/or attendance at appropriate post-graduate meetings/lectures/events etc.

Business Continuity

The provider must ensure that adequate arrangements are in place for continuity of the service in the event of staffing shortages, facilities, and system failures appropriate to the service to include subcontractors.

Significant Events

The Department of Health and social care emphasises the importance of collected incidents nationally to ensure that lessons are learned across the NHS. A proactive approach to the prevention of recurrence is fundamental to making improvements in patient safety.

The provider must have systems in place for documenting and learning from significant events, including reporting as appropriate.

The provider should be aware of the various reporting systems, such as:

- The National Patient Safety Agency National Reporting and Learning System.
- The Medicines and Healthcare Products Regulatory Agency reporting systems for adverse reactions to medication (yellow card system) and accidents involving medical devices.
- The legal obligation to report certain incidents to the Health and Safety Executive under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR).

In addition to their statutory obligations, the provider should give notification, within 72 hours of the information becoming known to him/her, of all emergency admissions or deaths of any patient treated by the provider under this service, where such admission or death is, or may be due, to the providers treatment of the relevant underlying medical condition covered by this specification.

6. Applicable Quality Requirements

The performance monitoring for this enhanced service is summarised below:

Latest Shared Care Guidelines are available from:

Detail	Evidence Required to Meet Indicator	Source of Evidence	Consequence of Breach	Frequency of Indicator
Validation confirmation must be submitted to: Monitoring of High Risk Drugs Data Validation Submission quarterly, by the 10 th day of the 1 st month of the following quarter	Quarterly submission	Practice	Delayed validation confirmation may result in payments being delayed or suspended.	Quarterly

<http://www.lancashireandsouthcumbriaformulary.nhs.uk/>

References

1. Safe management of therapeutic drug monitoring Published 2 October 2024 · Last updated 17 October 2024 <https://www.sps.nhs.uk/articles/safe-management-of-therapeutic-drug-monitoring/>
2. Specialist Pharmacy Service Medicines Monitoring <https://www.sps.nhs.uk/home/tools/drug-monitoring/>
3. NHS England, Regional Medicines Optimisation Committees advice. Shared Care Protocols [NHS England » Shared Care Protocols](#)
4. Summary of product characteristics - Electronic Medicines Compendium (eMC) <https://www.medicines.org.uk/emc>