Service Specification No.	**Domain 2A**
Service	**Near Patient Testing for High Risk/Amber Drugs Level 2**
Commissioner Lead	**NHS East Lancashire Clinical Commissioning Group (CCG)**
Provider Lead	**GP Practices in Pennine Lancashire**
Period	**1st July 2022 – 31st March 2024**
Date of Review	**April 2024**

1. Population Needs

1.1 National/Local Context and Evidence Base

It is important for patient care that there is a clear understanding of where clinical and prescribing responsibility rests between Specialists (*) and GPs. The East Lancashire Traffic Light scheme for medicines aims to support this, by providing guidance on who should initiate and then continue the prescribing of certain medicines. Medicines that have been designated with an AMBER traffic light level 2 are defined as follows:

AMBER Traffic Light (Level 2 Medicines)

These medicines are considered suitable for GP prescribing following specialist initiation of therapy and patient stabilisation, with on-going communication between GP and Specialist. Such medicines require intensive monitoring and to qualify must be designated so by the East Lancashire Medicines Management Board.

GPs are not advised to take on prescribing of these medicines unless they have been adequately informed by letter of their responsibilities with regards to monitoring, side effects and interactions and are happy to take on the prescribing responsibility.

Where a locally approved prescribing guidance document exists this should accompany this letter, which outlines these responsibilities. GPs should then inform Secondary Care of their intentions as soon as possible by letter, and then arrange the transfer of care as necessary.

Therefore, it is essential that a transfer of care involving medicines that a GP would not normally be familiar with should not take place without the 'sharing of information with the individual GP and their mutual agreement to the transfer of care'. This information is best provided in the form of an approved shared care protocol. The concept of drugs that GPs would not routinely initiate and therefore would not normally be familiar with is encompassed in *Dept. of Health EL(91)127 "Responsibility for prescribing between Hospitals and GPs*' http://www.elmmb.nhs.uk/shared-care-guidelines/

Additionally certain medications that might be initiated in Primary Care have monitoring requirements that must be fulfilled in order to ensure patient safety. These high risk drugs are included in this specification in order to ensure that patients receiving these treatments are getting the necessary and appropriate monitoring in order to achieve the best clinical outcomes.

(*) Specialists are those clinicians working within Secondary Care at Consultant grade, or GPs with a specialist interest (GPwSI) working in Primary Care prescribing only within their speciality.

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 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

3.1 Aims and Objectives of Service

The aims of the service are to offer near patient testing of medications deemed high risk and also AMBER drugs level 2. The service will offer enhanced aspects of clinical care to the patient.

Certain high risk medications which require annual monitoring including antipsychotics, carbimazole, hydroxychloroquine, mesalazine, NSAID's, phenytoin, propylthiouracil, sirolimus and tacrolimus fall outside this service specification as it would be expected that the annual monitoring for these drugs is undertaken as a core part of the individuals annual review.

Service Aims:

- The service to the patient is convenient whilst remaining clinically safe;
- Patients receive the necessary and appropriate monitoring at the right time;

  All 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 patients 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 the resources by the National Health Service is efficient.

3.2 Service Description/Care Pathway

This service will provide near patient testing associated with the prescribing of medicines designated as AMBER light level 2 or considered to be high risk and requiring more frequent monitoring than on an annual basis. (See Appendix A).

This service includes drugs for rheumatology patients commenced on DMARDS plus medicines designated locally 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 East Lancashire that are registered with an East Lancashire GP.

3.4 Any Acceptance and Exclusion Criteria

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

Lithium (also designated a level 2 amber medicine) is excluded from this specification as monitoring is funded via the QOF.

3.5 Interdependencies with other Services

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.

4. Applicable Service Standards

4.1 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.

4.2 Applicable Standards set out in Guidance and/or Issued by a Competent Body

As per the NHS Standard Contract.

Record and Information Keeping

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 Read Code to allow relevant audits to be conducted. Patients who are prescribed a drug listed in Appendix A and who receive the monitoring and/or adjustment of therapy by the practice should be read 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 payment is being claimed under this local enhanced service the following Read Code should be used:

66P7 High Risk Drug Monitoring – Primary Care

Where patients are receiving monitoring with or without adjustment of therapy by Secondary/Tertiary care and therefore payment is not being claimed under this local enhanced service the following Read Code should be used:

66P8 High Risk Drug Monitoring – Shared Care

Where treatment is stopped the following Read Code should be used:

66P6 High Risk Treatment Stopped

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.

4.3 Applicable Local Standards

Prescribing by a Primary Care prescriber of an Amber level 2 drug should normally be carried out in accordance with the guidance provided in the East Lancashire Monitoring Guidelines and/or the shared care protocol (where available) for that drug.

East Lancashire Monitoring Guidelines for AMBER level 2 drugs can be found online at:

http://www.elmmb.nhs.uk/guidelines/other-clinical-guidelines/

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

Adherence to them will not ensure a successful outcome in every case. The ultimate judgement regarding a particular clinical result must be made by the doctor in light of 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.

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 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.

Significant Events

The Department of Health emphasizes 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.

4.4 Monitoring and Reporting

The provider must supply the CCG with such information as it may reasonably request for the purposes of monitoring the provider's performance of its obligations under this service level agreement.

5. Payment

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 read 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 £70.00 per patient per year will be paid;

- For drugs that require between 3 and 6 monthly testing an annual fee of £35 will be paid;

- It is expected that drugs requiring 12 monthly monitoring are reviewed as part of the core annual clinical review so will not attract an additional payment;

- Payments will be made in 4 equal quarterly payments of £17.50 per patient for individuals on medication requiring 3 monthly monitoring and £8.75 per quarter per patient for those requiring 6 monthly monitoring.

This will be based on the number of patients on the practice's register at the beginning of the year. The practice is not required to submit a monthly claim in respect of this service. For patients receiving more than one of these drugs, only one payment per patient will be made.

The above payment is to cover:

- all staff time involved in undertaking the procedure;

- disposables/consumables associated with undertaking the procedure;

- all sterilisation/maintenance/calibration/servicing/repair/replacement and insurance of equipment.

Appendix A- High risk / Amber Medicines and recommended frequency of monitoring

Note these tables indicate suggested monitoring intervals for AMBER SHARED CARE drugs in line with the respective shared protocol. It only applies to the licensed and unlicensed indications listed in the protocol. Transplant prescribing is assigned a RED traffic light and relevant protocols should be followed for these indications.

Eplerenone (Inspra®) for Post-MI heart failure is **AMBER TRAFFIC LIGHT** (not shared care). Refer to the UKMI Therapeutic Drug Monitoring in Adults in Primary Care or the electronic Medicines Compendium (eMC) for monitoring requirements.

Drugs requiring 3 monthly or more frequent monitoring

Drug	Suggested monitoring interval	Indications
Azathioprine	3 months	Licensed: Rheumatoid arthritis, systemic lupus erythematosus, dermatomyositis and polymyositis, autoimmune and chronic active hepatitis, pemphigus vulgaris, polyarteritis nodosa, ITP and auto-immune haemolytic anaemia. Unlicensed: Polyarteritis and giant cell arteritis, psoriasis and psoriatic arthritis, severe eczema and other autoimmune skin conditions, inflammatory bowel diseases including ulcerative colitis and Crohn's disease,
Ciclosporin	Monthly	Licensed: Treatment of psoriasis and atopic dermatitis; rheumatoid arthritis and nephrotic syndrome Unlicensed: Severe ulcerative colitis – cited in NICE guidelines however use is declining
Hydroxycarbamide	3 months	Unlicensed: Psoriasis ONLY, other indications RED Traffic light
Leflunamide	3 months	Licensed: Treatment of active rheumatoid arthritis and active psoriatic arthritis.
Mercaptopurine	3 months	Unlicensed: Inflammatory bowel diseases.
Methotrexate	3 months	Licensed: Rheumatoid arthritis, severe psoriasis, severe active juvenile idiopathic arthritis, severe psoriatic arthritis, mild to moderate Crohn's disease Unlicensed: Severe Eczema, Lichen Planus, Felty's syndrome, severe Crohn's disease.
Mycophenolate	Monthly	Unlicensed: Severe rheumatoid arthritis, psoriatic arthritis, systemic lupus erythematosus, connective tissue diseases with severe / organ-threatening manifestations, interstitial lung disease (not to be used in idiopathic pulmonary fibrosis IPF), vasculitidies, as maintenance post cyclophosphamide in patients for whom azathioprine is contra-indicated or is inappropriate.
Penicillamine	Monthly	Licensed: Severe active rheumatoid arthritis, including juvenile forms, Wilson's disease (hepatolenticular degeneration) in adults and children (0 to 18 years).
Sodium Aurothiomalate	3 months	Licensed – Active, progressive rheumatoid arthritis, progressive juvenile chronic arthritis especially if polyarticular or seropositive. Unlicensed – skin diseases including pemphigus.

Drugs requiring 6 monthly monitoring

Drug	Suggested monitoring interval	Comments
Amiodarone	6 months	Supraventricular arrhythmias. Red Traffic for injections
Denosumab	6 months	Prolia® (60mg Denosumab only). Treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture.
Dronedarone	1-12 months	Supraventricular arrhythmias; atrial fibrillation.
Eplenerone	6 months	Post-MI heart failure.
Valproate/Sodium Valproate	6 months for rapid-cycling bipolar disorder only	For patients with bipolar disorder NICE additionally recommends TFTs (every 6 months if rapid-cycling) but otherwise every12 months. Annual monitoring is not eligible for claims.

Latest Shared Care Guidelines and Suggested Monitoring Table are available from:
http://www.elmmb.nhs.uk/policies-and-guidelines/shared-care-guidelines/

References

Suggested monitoring requirements for Adults in primary Care – UKMI Feb 2014
http://www.medicinesresources.nhs.uk/upload/documents/Evidence/Drug%20monitoring%20document%20Feb%202014.pdf

Suggestions for Therapeutic Drug Monitoring in Adults in Primary Care Published 8th December 2017, updated 16th April 2018
https://www.sps.nhs.uk/articles/suggestions-for-therapeutic-drug-monitoring-in-adults-in-primary-care/

electronic Medicines Compendium (eMC)
https://www.medicines.org.uk/emc