SCHEDULE 2 – THE SERVICES

A. Service Specification

Service Specification No.	LES1 AMB
Service	Amber Drugs Prescribing and Monitoring Service
Commissioner Lead	NHS Leeds Clinical Commissioning Group
Provider Lead	
Period	1st April 2022 to 31st March 2023
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

The Leeds CCG is committed to providing care closer to home, where this is clinically appropriate and more convenient for patients, and where this provides value for money to the health economy.

Services will be commissioned in line with the latest evidence base and providers will be required to ensure services meet all national regulatory requirements.

This service specification is for patients registered with a NHS Leeds Clinical Commissioning Group GP practice.

Some drug treatments for certain indications should be initiated by specialists. However many are suitable for transfer to ongoing prescription by General Practitioners (GPs) at an appropriate point. In Leeds, these drugs are known as Amber Drugs. The status of any drug in the Leeds NHS health economy is determined by the Leeds Area Prescribing Committee (LAPC), using published criteria on Leeds Health Pathways. (http://nww.lhp.leedsth.nhs.uk)

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

These services are being commissioned by the Leeds CCGs to support the following domains of the NHS Outcomes framework.

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

a) Improved access and convenience for patients.
b) Timely provision of test results where appropriate
c) Good information flows to referrers to enable appropriate ongoing management

3. Scope

The Service will operate in accordance with the principles of Amber Drugs Monitoring (see Annex1)

The Service relates to the associated monitoring of more specialist (drugs classed as Amber level 3 plus all oral anticoagulants) treatment. It includes all clinical indications for Amber Level 3 drugs on the list agreed by LAPC (available at http://nww.lhp.leedsth.nhs.uk/common/guidelines/detail.aspx?ID=55).

Monitoring related to co-prescribed drugs (not being amber drugs), other health conditions and the patient's general health is not included in this SLA

For the avoidance of doubt, it should be noted that a service provider who enters into Amber drugs monitoring agreements for the Amber drugs under this SLA is not thereby obliged to enter into shared care arrangements for other drugs.

Referrals to the Service

Monitoring responsibility relating to any individual patient will be transferred to the service provider only after the service provider has agreed regarding the named patient.

The specialist department seeking the Amber Drug monitoring arrangements will continue to prescribe and monitor treatment until transfer of responsibilities has been agreed.

The service provider must inform the specialist department within 14 days of the receipt of a written or e-mail request to enter into an Amber Drugs monitoring agreement if they are unwilling or unable to provide the service for that patient.

Record Keeping

A record must be kept of all of the patient's blood results (and the results of other relevant investigations or measurements) on a system that allows previous results to be accessed easily and trends observed. Records must be kept of all dose adjustments.

A record of what monitoring is required for the amber drug and when this monitoring should be undertaken should be made in the patient's notes. There should be system in place to ensure monitoring is being completed as recommended.

A record must be made when a patient is started on an amber drug. This should form part of a computerised database that allows for patient recall. Details must include:

- Name
- Date of Birth
- Address
- Contact telephone number
- Past Medical History
- Medication History
- Previous Blood Results
- Information relating to significant Events e.g. Hospital Admissions, death of which the practice has been notified, route of return and reasons

For certain specified medicines (such as methotrexate), the specialist who initiates the treatment should provide the patient with a monitoring booklet approved by the LAPC. This is to be kept by the patient and blood results (and as appropriate urinalysis results) should be recorded in it by the service provider.

If for any reason a patient has not received a booklet from the specialist department the service provider should supply one. (Booklets can be obtained from nhs forms at www.nhsforms.co.uk).

Information for the Patient

The service provider will be responsible for providing oral and/or written advice as appropriate regarding:

- The Service being provided and what the patient can expect from the service
- The drugs and potential side effects from these drugs.

If LAPC has approved a patient information leaflet (PIL), the service provider must provide the patient with

a copy of this PIL if the patient has not previously been provided with one by the specialist department.

Drugs Monitoring Requirements
All Amber level 3 drugs require regular monitoring. Amber Level 3 Drug guidelines have been developed by doctors and pharmacists from both primary and secondary care, which set out the monitoring requirements for most of these drug treatments. Monitoring of Amber Level 3 Drugs must be carried out under an Amber Drug monitoring agreement between the service provider and the specialist department seeking the Amber Drug monitoring arrangement.

Monitoring should be carried out at appropriate intervals as set out in the relevant Amber guidance approved by LAPC. If no Amber guidance has been developed a monitoring schedule must be proposed for each individual patient by the specialist department and agreed by the service provider.

It is the responsibility of the service provider and the specialist department to ensure that there is mutual clarity of understanding regarding respective responsibilities relating to the care of the individual patient. This may be by reference to the relevant Amber guidance or by letter or e-mail.

Blood Monitoring Arrangements
The patient must be given appropriate appointments to have blood taken, or for other appropriate monitoring, at a time and location suitable to the patient.

Where monitoring is being conducted by the specialist department this must be clearly stated and recorded. A copy of the hospital letter confirming this must be kept with the patient notes. If the Amber drug is being prescribed in primary care, the results of all relevant monitoring carried out by secondary care must be available in the patient records.

Any variation to monitoring arrangements (frequency or location) must be agreed between the patient, the service provider and the specialist department and recorded.

The service must have adequate patient recall facilities.

Patients must be identified and followed up if they do not attend to have blood taken, or any other monitoring appointment, as appropriate. Patients who miss appointments should be contacted at the earliest opportunity and another appointment made. The GP should use their clinical judgement to decide whether it is safe to continue to prescribe the amber drug whilst monitoring is outstanding, taking into account the risks to the patient associated with continuing or stopping treatment. The GP should inform the consultant of any problems relating to patient monitoring, and inform them if the prescription has been stopped.

Blood Analysis
If specified by the Amber guidance's the service provider will interpret the blood results, or results of other monitoring, and be responsible for making recommendations about further actions (i.e. repeat blood tests and dose changes) based on these results.

If no Amber guidance is in place, arrangements for interpretation and advice on dose changes must be made and agreed between the service provider and the specialist department.

Communication
The service provider will be responsible for communicating the results of blood tests or other monitoring and any further action required to the patient.

If a result is returned as abnormal, the provider must communicate with the patient within 1 working day of the result being received.

Interdependence with other services/providers
Access to and support from secondary care and primary care clinicians should always be accessible as circumstances allow. The Provider must demonstrate how clinical and supervisory links with related local secondary care departments will be achieved. This includes ensuring arrangements for timely access to pathology tests if appropriate.

Aims and objectives of service

The services will:

- Ensure equitable, timely and appropriate access
- Provide services that are the best value for money
- Ensure patients are seen and treated in a safe environment most appropriate to their care needs
- Deliver a cohesive and seamless pathway based on patient need
- Facilitate the shift of services closer to home through development and innovation
- Provide a streamlined patient referral process
- Ensure records are kept of any onward referrals by the Provider.

Future Development of the service

At the end of each year of operation of the service, it will be reviewed by LAPC

- Secondary to primary care shift in activity
- Any changes in legislation
- Patient feedback
- Practice feedback

Scheme Ongoing Monitoring and Evaluation

During the term of this agreement the commissioner and the provider will meet to ensure the requirements under of the contract are being met.

Activity and audit data will be provided to NHS Leeds Clinical Commissioning Group when requested to enable the CCG to monitor, evaluate and review performance.

The full Audit requirements can be found in Schedule 6 Part B – Reporting Requirements.

Financial Details

These can be found in Schedule 3 – Payment Appendix 1

4. Applicable Service Standards

It is essential for patient safety that Amber Drugs are prescribed only by GPs who understand and accept the clinical responsibility for that drug in that indication. The Department of Health has confirmed that clinical responsibility for the patient's response to treatment lies with the person who signs the prescription.

Applicable national standards (e.g. NICE)

Providers are required to ensure that they are fully aware of the relevant NICE and other national guidance related to the services they deliver, and to be fully compliant with these requirements, or to alert commissioners where they are not able to comply.

Accreditation, Competency and Training

Service providers who have previously provided services similar to this service and who satisfy at appraisal and revalidation that they have such continuing medical experience, training and competence as is necessary to enable them to provide this service shall be deemed professionally qualified to do so.

It is the responsibility of the service provider to make all reasonable efforts to acquire sufficient competence to provide the service safely and adequately in respect of the Amber drugs they agree to prescribe.

The specialist department seeking the Amber Drug monitoring arrangement will assist by offering any specific training which may be requested by the service provider, such as specialist injection techniques, etc.

Management of Emergencies

The Provider is expected to have carried out a risk assessment on the procedures carried out and to have procedures, protocols and action plans to mitigate against any identified risk. This may include but is not

limited to:

(a) an up to date, documented resuscitation policy and procedure formally adopted through an appropriate clinical governance process;

(b) all staff to be aware of the resuscitation procedure and to have received training in the application of the policy and procedure. The procedure to include details of how to summon staff to help and provide assistance in the event of clinical deterioration, collapse or cardiopulmonary arrest;

(c) all clinicians and clinical support staff to have received Basic Life Support Training, which is recorded, monitored and updated annually;

(d) resuscitation equipment that is appropriately situated and accessible, and is regularly maintained via a documented system.

(e) the Provider shall have a procedure in place to deal with any incidence of haemorrhage;

(f) the Provider shall have a policy in place for the transfer of patients in an emergency situation

(g) the Provider shall have a recognised incident reporting system in place and shall notify the Commissioner of any serious incidents within 24 hours.

Audit

The CCG will audit compliance with monitoring requirements using a series of monthly reports extracted from the clinical systems. These will be sample audits of one test per Amber Level 3 drug issued and are designed to be indicative of compliance but are not inclusive off the full range of tests required for all amber drugs.
Results of the monthly audit reports will be reported to the practices

Details of the audit schedule are in Schedule 6 Part B Process for Amber Level 3 Drug Payment and Audit
The target for attainment is 80% compliance. **Practices that fail to demonstrate 80% compliance with monitoring requirements will need to submit an action plan for improvement. Failure to submit action plans or consistently poor results poor results may result in loss of amber payments.**

The provider must allow the commissioner, or any individual or organisations acting on the behalf of the commissioner to inspect the quality of service through observation of service delivery, audit of patient records and data, audit of business processes and records relating to the service contract and audit of staff records, as required.

The provider must notify the commissioner of the result of any audit undertaken by any regulating body, or any other NHS commissioner.

5. Applicable quality requirements

See Schedule 4

6. Location of Provider Premises

The Provider's Premises are located at: XXXXXXXX

Annex 1 – Principles of Amber Drugs Monitoring

1. Introduction

Application of the following principles will facilitate effective Amber drug monitoring. However, it should be noted that GPs are not obliged to enter into Amber drug monitoring arrangements for a particular patient simply because the relevant drug has an amber classification. The Department of Health has confirmed

that clinical responsibility for the patient's response to treatment lies with the person who signs the prescription.

2. Principles of Amber drug monitoring Management

2.1. Best interest of the Patient

The best interests of the patient should be at the centre of any Amber drug monitoring management agreement. Arrangements should never be detrimental to or inconvenient for the patient.

2.2. Individual, patient by patient arrangements

Amber prescribing guidelines should be accompanied by individual patient information, outlining all relevant aspects of that patient's care.

2.3. Reasonably predictable clinical situation

Transfer of clinical responsibility to primary care should be considered only where a patient's clinical condition is stable or predictable

2.4. Willing & informed consent of all parties, including patients and carers

All parties to the agreement must have sufficient, accurate, timely information in an understandable form. Consent must be given voluntarily. Specialists and general practitioners are encouraged to communicate with each other directly where questions arise around shared care for a particular patient. If issues remain, after these discussions, the department of the Chief / Senior Pharmacist at the CCG or Hospital Trust should be contacted for advice.

2.5. Clear definition of responsibility

The areas of care for which each partner in the arrangement has responsibility should be clearly defined and should be patient specific

2.6. Communication network & emergency support

Appropriate contact details should be provided to enable GPs to contact specialists readily, including (where appropriate) out-of-hours arrangements

2.7. Clinical information

This should include a brief overview of the disease and more detailed information on the treatment(s) being transferred including (as a minimum):

- Where the treatment is not licensed for any indication in the UK, or is licensed for other indications but not this indication, a note to this effect with an indication of the strength of evidence to support its use for this indication
- Dose, route of administration and duration of treatment
- Common adverse effects (incidence where known, identification, importance and management)
- Monitoring requirements and responsibilities
- Clinically important drug interactions and their management
- Contacts for more detailed information

2.8. Training

It is the responsibility of the service provider to make all reasonable efforts to acquire sufficient competence to provide the Service safely and adequately. The specialist department seeking the shared care arrangement will assist by offering any specific training which may be requested by the service provider, such as specialist injection techniques, etc

2.9. Review

Amber guidance will be reviewed every two years or more frequently if indicated.

3. Involving the Patient

The consultant should obtain the consent of the patient (and his/her carers if appropriate) only after the GP has agreed in principle to sharing management. Patients should never be used as a conduit for informing the GP that prescribing is to be transferred, nor should they be placed in a position where they are unable to obtain the medicines they need because of lack of communication between primary and secondary/ tertiary care.

4. Agreement of Amber drug monitoring management between specialist and GP

Monitoring, responsibility relating to any individual patient will be transferred to the GP only if the GP has agreed regarding that named patient. The specialist department seeking the Amber drug monitoring

management arrangement will continue to prescribe and monitor treatment until transfer of responsibilities has been agreed. The GP must inform the specialist department within 14 days of receiving the written or e-mail request if it is unwilling or unable to provide the Service for that patient, with reasons.

5. Health equality and Amber drugs that required administration

Patient health equality must always be considered before refusal to accept transfer of prescribing and monitoring responsibilities from secondary care. Refusal should not be made solely because a drug also requires administration by the practice, for example depot antipsychotic medication.

Appendix 1: Banding criteria

Banding	Payment per drug patient per year	Typical monitoring requirements
Band 1	£80	Monitoring every one-two months of U&Es, LFTs, FBCs. Include ECG, respiratory function tests etc. Verbal interview and record keeping of symptom checklist. Reporting of concerns to specialist.
Band 2	£40	Monitoring more than twice a year up to and including every three months. Include ECG, respiratory function tests etc. once a year. Verbal interview and record keeping of symptom checklist. Reporting of concerns to specialist.
Band 3	£20	Monitoring twice a year or less often Two or more of the following: U&Es, LFTs, FBCs Verbal interview and record keeping of symptom checklist. Reporting of concerns to specialist. *New banding level for all oral anticoagulants / all indications*
Band 4	£66	Depot Antipsychotic Drugs administered by practice every 2 weeks
Band 5	£40	Depot Antipsychotic Drugs administered by practice less often than every 2 weeks.
Band 6	Nil	None or little monitoring required in primary care

Drugs and banding classification.

Amber Level 3 Drug	Payment Band	Comment
Agomelatine	3	*New for 22.23*
Amiodarone Hydrochloride	3	
Amisulpride	3	
Apixaban	3	
Aripiprazole oral	3	
Aripiprazole depot	5	
Atomoxetine Strattera®	2	
Azathioprine	2	
Benperidol	3	
Carbamazepine mood stabiliser only	3	
Chlorpromazine	3	
Ciclosporin	2	*Changed from band 1 in Q2 21.22 as all A3 documents now same 3 monthly monitoring*
Cinacalcet	2	
Cyproterone for gender dysphoria	3	
Dabigatran	3	
Danazol (angiodema only)	6	
Dapsone	2	
Demeclocycline for SIADH only	2	
Denosumab (Prolia)	2	
Dexamfetamine Sulphate	2	
Dronedarone	3	
Edoxaban	3	
Enoxaparin	3	
Entecavir	3	
Estradiol patch (gender dyphoria only)	3	
Estradiol Tablets 1 and 2mg (gender dysphoria only)	3	
Flupentixol oral	3	
Flupentixol Decanoate depot	4 or 5	
Fluphenazine Decanoate depot	4 or 5	
Guanfacine - Adults	3	
Haloperidol oral	3	
Haloperidol depot	4 or 5	
Hydroxycarbamide	2	
Hydroxychloroquine/chloroquine	6	
Ibandronic acid 50mg tablet	6	
Ketoconazole	6	

Lamivudine	3	
Lanreotide	2	
Lanthanum	3	
Leflunomide	2	
Leuprorelin/Goserelin for gender dysphoria only	2	
Levamisole (nephrotic syndrome in children)	3	
Levomepromazine	6	
Liothyronine	3	
Lisdexamfetamine	2	
Lithium	2	
Mepacrine	3	*New for 22.23*
Mercaptopurine	2	
Mesalazine oral	3	
Methotrexate oral	2	
Methylphenidate hydrochloride	3	*Band change from Band 2 as monitoring changing from 3 to 6 monthly*
Metyrapone	2	
Mexiletine	3	
Modafinil	3	
Mycophenolate Mofetil	2	
Octreotide	2	
Oestrogel for gender dysphoria only	3	
Olanzapine oral	3	
Paliperidone depot	5	
Penicillamine	2	
Pericyazine	3	
Perphenazine	3	
Pimozide	3	
Prochlorperazine	6	
Promazine Hydrochloride	3	
Quetiapine oral	3	
Riluzole oral	3	
Risperidone oral	3	
Risperidone depot	4 or 5	
Rivaroxaban	3	
Sacubitril valsartan	3	
Sevelamer	3	
Sirolimus	3	
Somatropin	3	
Spironolactone gender dysphoria only	3	
Stiripentol	3	
Sucroferric oxyhydroxide	1	
Sulfasalazine adults	6	
Sulfasalazine children	2	
Sulpiride	3	

Tacrolimus	3	
Tenofovir	3	
Testosterone enantate gender dyshoria only	2	
Tinzaparin	3	
Trifluoperazine	3	
Valproic Acid/Sodium Valproate Depakote/Eplilim/Episenta brands only Bipolar only	3	
Venlafaxine > 300mg only	6	
Warfarin	3	
Zuclopenthixol Decanoate Depot	4 or 5	
Zuclopenthixol oral	3	