SCHEDULE 2 – THE SERVICES

A. Service Specification

Service Specification No.	**FINAL**
Service	Amber Drugs Prescribing and Monitoring Service
Commissioner Lead	NHS West Yorkshire Integrated Care Board
Provider Lead	
Period	1st April 2025 to 31st March 2026
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

The West Yorkshire Integrated Care Board (ICB) 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 practice commissioned by the NHS West Yorkshire ICB. This includes Bradford, Calderdale, Kirklees, Leeds, and Wakefield places.

Amber medicines should only be initiated by a specialist and require specific monitoring on an ongoing basis. Amber medicines are considered suitable for transition to GP prescribing after initiation and stabilisation. Full agreement to the transfer of prescribing and monitoring responsibilities of each specific patient must be reached under the amber drug agreement, and amber drug guidance must be provided to the GP. Since the formation of the West Yorkshire ICB Area Prescribing Committee (WYAPC), drug classifications are determined by the WYAPC using criteria published on www.wyicsapc.co.uk.

Some drugs are still pending harmonisation of their classification through WYAPC. Until a harmonised classification is agreed for all drugs, there will be some variation in classifications of specific drugs across places (See *Appendix 2 – Table 2, 3 & 4* for place specific variations in classifications).

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

These services are being commissioned by WY ICB 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

Please note: Since the formation of the WYAPC, Traffic Light classification definitions are being reviewed and harmonised across the West Yorkshire ICB. This local commissioned service (LCS) relates to the associated monitoring of specialist drugs classed as Amber (in Leeds place formerly Amber Level 3)

It includes all clinical indications for Amber drugs (formerly Amber Level 3) on the list agreed by WYAPC and available on www.wyicsapc.co.uk (also available in Leeds at http://nww.lhp.leedsth.nhs.uk/common/guidelines/detail.aspx?ID=55).

Referrals to the Service

The specialist will send a written request (includes clinic letter, email and/or clinical system task) to the service provider to enter into an Amber Drugs monitoring agreement.

The service provider must inform the specialist within 14 days of the receipt of a written request if they are unwilling or unable to provide the service for that patient. If the service provider has not contacted the specialist within 14 days the specialist will class, the lack of response as agreement of the provider to prescribe and monitor the medication as per the amber guidance.

Prescribing and monitoring responsibility relating to any individual patient will be retained by the specialist if a transfer of responsibilities is declined by the service provider. There may be a need for additional information or support to be provided to the service provider or alternative arrangements may need to be agreed.

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.

There should be an appropriate recall system and processes in place to ensure monitoring is completed as outlined in the amber guideline or by the specialist (if different).

For certain specified medicines (such as methotrexate), the specialist who initiates the treatment may provide the patient with a monitoring booklet. This is to be kept by the patient and blood results (and as appropriate urinalysis results) may be recorded in it by the service provider as appropriate.
Booklets can be obtained from NHS forms at www.nhsforms.co.uk.

Information for the Patient
The specialist should ensure that patients have access to information including any specific patient information leaflet, regarding the drug and potential side effects as per the amber guideline and are aware of patient responsibilities under the amber guideline.

Drugs Monitoring Requirements
All Amber drugs require regular monitoring. Amber Drug guidelines have been jointly developed by healthcare professionals from both primary and secondary care, which set out the monitoring requirements for these drug treatments. Monitoring of Amber Drugs must be carried out as specified 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 WYAPC.

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.

Monitoring Arrangements
The patient must be given appropriate appointments to have blood taken, or for other appropriate monitoring.

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 or primary care prescriber 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, seeking specialist advice where appropriate. The GP or primary care prescriber should inform the consultant of any problems relating to patient monitoring and inform them if the prescription has been stopped.

Analysis of Monitoring Results
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.

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 and requires further action, the provider must communicate with the patient in a timescale that reflects the urgency of the issue identified. Practices should have systems and processes in place to act upon urgent results.

Interdependence with other services/providers
The specialist department must demonstrate how they will be accessible to primary care clinicians, to enable timely access to support. The Provider must demonstrate how clinical and supervisory links with related specialists will be achieved.

This includes agreeing joint arrangements for timely access to pathology tests, follow up and specialist advice as required.

If the provider finds that the specialist department is not providing adequate timely access to support to enable shared care of the patient to safely continue, it should alert the ICB for escalation.

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
- Support delivery of services closer to home

- Ensure clear communication and delivery of responsibilities by provider and specialist

Future Development of the service
Amendments to the amber drug list within the scope of this service will be made by WYAPC with representation from all providers and provider representative groups as part of decision making.

The scheme will be reviewed on an annual basis.
Scheme Ongoing Monitoring and Evaluation
The provider is responsible for ensuring delivery of the service in line with the monitoring requirements within each amber guideline. This includes undertaking an annual audit (Appendix 4). Audits should be used as part of provider quality improvement and received at the appropriate governance meetings within the provider. They should be retained and available to WYICB as part of ongoing assurance processes or post payment verification. See Audit details in section 4 (Applicable Service Standards) and appendix 4 for details.

Financial Details
These can be found in Appendix 1: Banding Criteria and Appendix 2: Drugs Banding Classifications

4. Applicable Service Standards

It is essential for patient safety that Amber Drugs are prescribed only by suitably qualified prescribers (see accreditation below) 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. CQC, NHSE, NICE)
Providers are required to ensure that they are fully aware of the locally agreed amber guidance and know where to access further information (e.g. NICE) if required.

Providers are required to ensure processes relating to amber drugs are in line with CQC requirements. The CQC produces a suite of GP Mythbuster Guides to support practices in ensuring best practice (available here: https://www.cqc.org.uk/guidance-providers/gps/gp-mythbusters). Mythbuster 12 covers 'Accessing medical records and carrying out clinical searches' which the CQC uses to assess the quality of care during their inspections. Checks relating to amber drug monitoring look for evidence of the following (not exhaustive):

- Medicines are appropriately prescribed and monitored in according to specific requirements
- Patients receive advice about their medicines and medicines reviews are in line with national guidance
- Test results are processed appropriately
- Correspondence is reviewed in a timely manner to make informed clinical judgements
- The practice has robust processes in place to identify patients affected by patient safety alerts or updates from the Medicines and Healthcare products Regulatory Agency (MHRA) such as those available here: https://www.gov.uk/health-and-social-care/medicines-medical-devices-blood-vigilance-safety-alerts.

Providers must ensure they are familiar with, and working in line with, NHSE guidance on "responsibility for prescribing between Primary & Secondary/Tertiary Care" https://www.england.nhs.uk/wp-content/uploads/2018/03/responsibility-prescribing-between-primary-secondary-care-v2.pdf

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 or non-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.

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 1 working day.

Audit
Details of the audit schedule are in *Appendix 4: Amber Drug Audits*
The target for attainment is a minimum of **80%** compliance.

Practices that fail to achieve 80% compliance with monitoring requirements will need to submit an action plan for improvement and may be required to undertake additional audits to demonstrate improvement. Failure to submit action plans or consistently poor results may result in loss of amber payments and withdrawal of the service.

The WYICB will audit compliance with monitoring requirements including through the use of reports extracted from the clinical systems.

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 relevant audit undertaken by any regulating body, or any other NHS commissioner.

Payment
Payments will be made based on the data extractions from the Clinical System to support reductions in administrative processes for practices. The clinical system searches will be made available to practices.

Payments will be calculated and paid quarterly by the ICB based on the number of patients on each of the amber drugs, adjusted for the appropriate tiered banding payment (Band 1, 2 or 3).

Data Extraction Dates:
1st April (Based on Q4 previous 3 months activity – Jan / Feb / Mar). Payment Date: 19 May (PMS) & 31 May (GMS)

1st July (Based on Q1 previous 3 months activity – Apr / May / Jun). Payment Date: 19 August (PMS) & 31 August (GMS)

1st October (Based on Q2 previous 3 months activity – Jul / Aug / Sep). Payment Date: 19 November (PMS) & 31 October (GMS)

1st January (Based on Q3 previous 3 months activity – Oct / Nov / Dec). Payment Date: 19 February (PMS) and 28 February (GMS).

Compliance with monitoring requirements is set at a threshold of 80%, allowing for 20% variation to cover instances where blood results may not be in the GP clinical system e.g. bloods done by secondary care. Payments may be withheld if compliance with monitoring requirements falls below 80% and remains without improvement and/or there is a failure to produce an appropriate action plan. The ICB will always aim to work collaboratively with practices to address any areas of improvement.

Classifications of medications and recommended monitoring frequency and/or requirements are subject to change. The specification and clinical system searches will be updated following any additions/deletions/amendments ratified through the WY ICS APC.

The WY ICS APC bulletin outlining all changes to amber classifications and updated amber guidance is published within 10 working days following APC and available on the **Website Address: /apc-bulletin/**

Following APC changes, the end of quarter data extraction would not reflect changes in the quarter. Payments would not be adjusted until the following quarter data extraction.

e.g. End of Q1 data extraction (run on 1st Jul - based on Q1 Apr/May/Jun)
APC changes ratified within Q1 would be made to specification and searches after 1st July data extraction.
Changes to payments will come into effect from start of Q2 (Jul / Aug / Sep) - data extraction 1st Oct.

NB: Practices are expected to comply with changes to amber drug requirements ratified through APC once live on APC website - irrespective of the payment start date.
When an amber classification or monitoring requirements are changed mid quarter e.g. change to banding tier – up or down, reimbursement will be made at the new rate the following quarter.

In order for the ICB to extract data for payment and Quality Assurance purposes, practices agree to data sharing agreement (non-patient identifiable) with the ICB.

5. Applicable quality requirements

See Schedule 4

6. Location of Provider Premises

The Provider's Premises.

As set out in the GMS/PMS contract, the Contractor should ensure that the premises in which services are to be provided must be suitable for delivery of those services and sufficient to meet the reasonable needs of patients.

The premises must also meet all current premises related Regulations 2024 Premises Cost Directions and any subsequent publications:

The National Health Service (General Medical Services - Premises Costs) Directions 2024

The Contractor should also ensure it has appropriate arrangements for infection control and decontamination.

Appendix 1: Banding criteria

Banding	Payment per drug patient per year	Typical monitoring requirements
Band 1	£233.15 per annum	Monitoring every one-two months as specified in the amber guidance Annual medication review to check compliance, symptom control and side effects etc. in line with monitoring requirements of Amber Guideline Reporting of concerns to specialist.
Band 2	£121.62 per annum	Monitoring more than twice a year up to and including every three months as specified in the amber guidance Annual medication review to check compliance, symptom control and side effects etc. in line with monitoring requirements of Amber Guideline Reporting of concerns to specialist.
Band 3	£65.86 per annum	Monitoring once or twice a year as specified in the amber guidance Annual medication review to check compliance, symptom control and side effects etc. in line with monitoring requirements of Amber Guideline Reporting of concerns to specialist.

Appendix 2: Drug banding classification

Table 1 – Harmonised

Amber Drug	Payment Band	Comment
Agomelatine	3	
Amiodarone Hydrochloride	3	
Atomoxetine	2	*Children aged 10 years and under*
Atomoxetine	3	*Children over 10 years, young people and adults*
Azathioprine	2	
Ciclosporin	2	
Cinacalcet	2	
Dapsone	2	
Denosumab (Prolia)	3	
Dexamfetamine Sulphate	2	*Children 10 years and under*
Dexamfetamine Sulphate	3	*Children over 10 years, young people and adults*
Disulfiram	3	
Dronedarone	3	
Guanfacine	3	*ADHD Children over 10years, young people and adults*
Guanfacine	2	*Children 10 years and under*
Hydroxycarbamide	2	
Hydroxychloroquine/chloroquine	3	
Lanreotide	2	
Lanthanum	3	
Leflunomide	2	
Levamisole (nephrotic syndrome in children)	3	
Liothyronine	3	
Lisdexamfetamine	2	*Children 10 years and under*
Lisdexamfetamine	3	*Children over 10 years, young people and adults*
Lithium	2	
Mepacrine	3	
Mercaptopurine	2	
Methotrexate oral	2	
Methylphenidate hydrochloride	2	*Children 10 years and under*
Methylphenidate hydrochloride	3	*Children over 10years, young people and adults*
Modafinil	3	
Mycophenolate Mofetil	2	
Octreotide	2	
Patiromer powder for oral suspension	1	*Hyperkalaemia in adults with HF or CKD Stage 3b - 5 (not on dialysis). Monthly U+Es*
Penicillamine	2	
Riluzole oral	3	
Sevelamer	3	
Sirolimus	3	
Sodium zirconium cyclosilicate powder for oral suspension	1	*Hyperkalaemia in adults with HF or CKD Stage 3b - 5 (not on dialysis). Monthly U+Es*
Low Molecular Weight Heparin (tinzaparin, dalteparin & enoxaparin)	1	*Treatment of VTE with DVT or PE or other conditions where anticoagulation is required, and alternative treatments are not suitable. Extended treatment & prophylaxis of VTE in adult patients with solid tumors*

Table 2: Awaiting Harmonisation - Kirklees, Wakefield and Calderdale Only

Naltrexone	Maintain abstinence in alcohol dependent patients	Band 3
Acamprosate	Maintain abstinence in alcohol dependent patients	Band 3
Bicalutamide	Locally advanced prostate cancer at high risk of disease progression. Locally advanced non-metastatic prostate cancer when surgical castration or other medical intervention is inappropriate. Ongoing monotherapy for prostate cancer in patients wishing to preserve sexual function. Maximum androgen blockade – use continuously in conjunction with LHRH analogue for three months	Band 3
GnRH Agonists Leuprorelin or Triptorelin GnRH analogues (Goserelin,Leuprorelin or Triptorelin), GnRH antagonist (Degarelix) Triptorelin	Endometriosis or uterine fibroids. Management of prostate cancer. Precocious puberty	Band 3
Melatonin	Treatment of sleep disorders in children and young people under 18 years.	Band 3
Cyproterone	Prostate cancer & male hypersexuality existing patients only	Band 3
Sulfasalazine	Rheumatoid Arthritis	Band 3
Colistimethate sodium - (Colomycin®)	Cystic fibrosis (CF) management	Band 3
Colistimethate sodium - (Promixin®)	Cystic fibrosis (CF) management	Band 3
Colistimethate sodium- (Colomycin®)	Pseudomonas infection in the lungs	Band 3
Danazol	The treatment of Hereditary Angioedema (HAE)	Band 3
Flupentixol depot injection	For treating schizophrenia, bipolar disorder, and other psychoses	Band 3
Somatropin for adults	Acquired adult-onset post-surgery growth hormone deficiency *Please note that Omnitrope® is what we commission in adults as growth hormone product of choice*	Band 3
Tacrolimus (oral)	Immunosuppressant for transplant patients. Post paediatric renal transplant, Nephrotic Syndrome in children	Band 3

Appendix 4: Amber Drug Audit

Amber Drug Prescribing Practice Audit

Practice Name:			
DATE COMPLETED:		**Complete the audit for 10% of patients or first 10 (whichever is greater) on the Shared-Care Register:**	

Pseudonym	Name of shared-care drug (if a patient is on more then 1 shared-care drug please use a separate line for each drug)	Dose	Level or levels of monitoring claimed e.g. 1,2,3	Have the minimum monitoring requirement been met? (*see appendix 1**) Y/N	Date of last monitoring tests	Is it documented in the patients record that the patient is on a shared-care drug? Y/N	Was the patient referred back to secondary care due to problems with the shared-care drug? Y/N If yes please give details
				Y/N	dd/mm/yyyy	Y/N	Y/N
Example 1	*Methotrexate*	*7.5mg weekly*	*Level 3*	*N*	*01.02.2016*	*Y*	*N*

To check individual guidelines, refer to the South West Yorkshire Area Prescribing Committee website

Lithium Prescribing Practice Audit

Practice Name:			
DATE COMPLETED:		**Complete the audit for all patients currently prescribed Lithium:**	

Pseudonym	Brand name of Lithium prescribed	Date and result of last recorded Lithium level *(every 3-6 months) target Lithium level 0.6-1.0		Date of last Renal function test**	Date of last Thyroid function test**	Date of last blood pressure test (every 12 months)	Date of last calcium (every 6 months)	Was any test missing or result was abnormal?	If any test was missing or abnormal was action was taken? Please give details and follow up results if applicable
		Date	Level	Date	Date	Date	Date	Y/N	
Example 1	*Priadel*	*21.04.2016*	*0.86*	*15.10.2015*	*15.10.2015*	*15.10.2015*	*15.10.2015*	*Y*	*Lithium level repeated*

*Check lithium level every 3 months for: Older people (over 65s), People taking drugs that interact with lithium (e.g. NSAIDS, diuretics, ACE inhibitors), People who are at risk of impaired renal or thyroid function, raised calcium levels or other complications such as significant cardiac disease, People who have poor symptom control, People with poor adherence or People whose last plasma lithium level was 0.8 mmol per litre or higher

**Every 6 months or more often if evidence of deterioration