SCHEDULE 2 – THE SERVICES

Service Specifications (B1)

Service Specification No.	03_CVDS_22
Service	Near Patient Testing
Commissioner Lead	CVDS CCP
Provider Lead	
Period	1ST April 2014 to 31/3/2015
Date of Review	1/10/14

Population Needs

National/local context and evidence base

The treatment of several autoimmune diseases, particularly in rheumatology but increasingly in other specialities such as gastroenterology and respiratory medicine, is increasingly reliant on drugs that are clinically effective but entail regular monitoring. This is due to the potentially serious side effects that these drugs can occasionally cause. It has been shown that the incidence of side effects and risk to patients can be reduced significantly if this monitoring is carried out in a systematic and well-organised way.

It is important for patient care that there is a clear understanding of where clinical and prescribing responsibility rests between specialists and GPs. The Dorset Traffic Light scheme for medicines aims to support this by providing guidance on who should initiate and then continue the prescribing of certain medicines categorised as amber.

This specification relates to the monitoring of patients on specified drugs designated as AMBER and monitored as part of a shared care arrangement. These are medicines which are considered suitable for GP prescribing following specialist initiation of therapy and patient stabilisation with ongoing communication between GP and specialist. Such medicines require intensive monitoring and to qualify must be designated so by the Bournemouth, Dorset and Poole Health Technologies Forum. GPs are advised not 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 shared care guideline exists this should accompany the letter which outlines these responsibilities. GPs should then inform secondary care of their intentions as soon as possible by letter if they do not wish to participate. GPs can refuse if they do not feel clinically confident to take on this prescribing.

All practices are expected to provide essential and those additional services they are contracted to provide to all their patients. This Local Contract for Drug Monitoring in Primary Care outlines the more specialised services to be provided. 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

and the Quality and Outcomes Framework or funded under other Enhanced Service provision. No part of the specification by commission, omission or implication defines or redefines essential or additional services.

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 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

Scope

Aims and objectives of service

The service aims to enable patients, whose drug therapy entails intensive monitoring, to access a safe, effective and convenient service close to home.

The primary care drug monitoring service is designed to be one in which:

All clinicians involved are confident in accepting the legal and clinical responsibility associated with the prescribing of these medicines;

therapy should only be started for recognised indications

maintenance of patients first stabilised in the secondary care setting, or in primary care under specialized guidance, should be properly controlled thereafter;

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;

the therapy is discontinued when appropriate.

Service description/care pathway

The service will deliver a Shared Care Drug Monitoring Service for patients prescribed one of more of the drugs set out in Annex 1.

The five disease modifying anti-rheumatic drugs (penicillamine, auranofin, sulphasalazine, methotrexate and sodium aurothiomalate) that are also designated as Amber medicines were included in a separate national specification but are now included in this agreement. Lithium, however, which is

a designated level 2 amber medicine is not part of this specification. Monitoring for this is funded via QOF.

Prescribing by a primary care clinician of an Appendix 1 listed drug should normally be carried out in accordance with the guidance provided by the Bournemouth, Dorset and Poole Health Technologies Forum and/or the shared-care protocol (where available) for that drug. Monitoring must be done under a shared care agreement between the GP and the patient's consultant. This agreement must specify the roles and responsibilities of the GP and the hospital with regards to monitoring. The monitoring should be done at appropriate intervals in accordance with a Prescribing/ Shared Care Framework. However, on occasions, specialists and GPs may agree to work outside of these guidelines for that drug if circumstances make this appropriate.

Dorset Monitoring Guidelines for AMBER level 2 drugs can be found on line at http://www.dorsetccg.nhs.uk/aboutus/medicines-management/traffic-light-scheme.htm and provides best practice guidance for monitoring these drugs. 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 doctor in light of the clinical data presented by the patient and the diagnostic and treatment options available and with advice from secondary care. Reference information on Amber drugs is available on the website of http://www.medicines.org.uk/emc/

The service will be available to patients registered at the practice participating in this contract.

Each episode must be recorded in the lifelong patient record.

All practices providing this service must comply with the following requirements:

Practices should be able to produce and maintain an up-to-date **register** of all patients receiving one of the medications and managed as part of a shared care arrangement listed in Annex 1. As well as the patient's demographic details, the register must include the indication for the relevant treatment, date of the last hospital appointment, medication history and duration of treatment, previous blood results on a system that allows results to be accessed easily and trends observed. Patients who are prescribed a drug listed in appendix 1 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 of therapy by secondary care/tertiary centre in order to differentiate those cared for under the shared care arrangement;

each patient must have an up to date **individual management plan**, agreed with secondary care, which gives the reason for treatment, the planned duration, the monitoring timetable and, if appropriate, the therapeutic range to be obtained;

each patient should have a **patient held record** which incorporates the management plan, particularly those required by NPSA alerts, including methotrexate;

the practice must have in place a systematic approach to ensuring that the **call and recall** of all patients on this register is taking place in line with the monitoring requirements and the patient's individual care plan;

the practice must ensure that all newly diagnosed/treated patients (and/or their carers where appropriate) receive **education and advice** on the management of, and prevention of, secondary complications of their condition. This should include written information where appropriate. The practice must ensure that all patients (and/or their carers and support staff when appropriate) are informed of how to access appropriate and relevant information throughout the course of their care;

all involved have a responsibility to maintain appropriate **professional links**, especially with secondary care colleagues involved in the patient's care;

the practice should have clear **referral policies** to ensure that, where appropriate, patients can be referred promptly to other necessary services and to the relevant support agencies using locally agreed guidelines where these exist;

the practice must maintain **adequate records** of the service provided, incorporating all known information relating to any significant events e.g. hospital admissions, death, of which the practice has been notified;

the practice should perform an **annual review** which could include:

- brief details as to arrangements for each of the aspects highlighted in the service specification
- details as to any computer-assisted decision-making and/or near-patient testing equipment used and arrangements for internal and external quality assurance
- details of training, education and professional development relevant to the drug monitoring service
- details of the standards used for the control of the relevant condition
- audit of compliance with those standards
- assurance that any staff member responsible for prescribing must have developed the necessary skills to prescribe safely.

Any acceptance and exclusion criteria and thresholds

A practice may be accepted for the provision of the contract if it has a partner, employee or sub-contractor who has the necessary skills and experience to undertake the required patient monitoring.

Practitioners who can demonstrate that they are currently providing this service for their patients will initially be accepted for continuing provision of this contract if they wish to continue to provide. Practices not currently providing this service will be required to demonstrate the required competences prior to arrangements being put in place to commission the service from the practice.

The Provider must have adequate mechanisms and facilities, including premises and equipment, as are necessary to enable the proper provision of this service. The provider shall provide any clinical equipment required. This should be maintained in accordance with the manufacturer's guidance and best practice and, where appropriate, recalibrated annually.

The clinician providing the services must demonstrate the relevant competencies to do so. Clinicians undertaking diagnostic tests, assessments and initiating and administering treatment must be adequately trained and supervised and have a

responsibility for ensuring that their skills and knowledge are regularly updated.

Practitioners 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. Evidence should be retained of continuing professional development in relation to this service specification and this may be required to be produced as evidence for accreditation or re-accreditation.

Interdependence with other services/providers

Applicable Service Standards

4.1 Applicable national standards (eg NICE)

4.2 Applicable standards set out in Guidance and/or issued by a competent body (eg Royal Colleges)

4.3 Applicable local standards

The service provider will:

demonstrate compliance with all relevant national standards for service quality and clinical governance including compliance with the NHS Standards for Better Health Framework and relevant NICE guidelines and any NPSA alerts;

demonstrate that a system of clinical governance and quality assurance is in place;

ensure that staff providing the service are suitably qualified and competent and have received the necessary training to deliver the service and that there are in place appropriate arrangements for maintaining and updating relevant skills and knowledge and for supervision – see Accreditation and Eligibility to Provide the Service;

ensure that lines of professional and clinical responsibility and accountability are clearly identified

ensure that all premises and equipment used for the provision of the enhanced service are at all times suitable for the delivery of those services and sufficient to meet the reasonable needs of patients or clients. This includes provision of a suitable room, with couch and sufficient space and equipment for resuscitation if required.

practices must follow infection control policies that are compliant with national and local guidelines. All infection control, decontamination measures and sterilisation of equipment must meet the standards within the Health and Social Care Act (2008) and its associated “Code of Practice for Health and Social Care on the Prevention and Control of Infections and related guidance”.

comply with Section 11 Children Act 2004 and associated Guidance issued by the Secretary of State, in part summarised in the document “Duty of Contractors

and Commissioned Service Providers to Safeguard and Promote the Welfare of Children"

comply with monitoring arrangements designed to ensure compliance with the Children Act 2004, as required on the part of the commissioner

ensure that relevant safety alerts and Medical & Healthcare Products Regulatory Agency (MHRA) notices are circulated to staff and acted upon where necessary

ensure that an effective complaints procedure for patients is in place , in line with the current NHS Complaints Procedure guidance, to deal with any complaints in relation to the provision of the enhanced service

ensure that a process is in place for any member of the professional team to raise concerns in a confidential and structured way

demonstrate a robust information service/source for patients and review regularly based on patient feedback

ensure that patients are able to contribute to the planning of their own care and that opportunities for feedback are easily available

ensure that treatment, care and information provided is culturally appropriate and is available in a form that is accessible to people who have additional needs, such as people with physical, cognitive or sensory disabilities, and people who do not speak or read English.

ensure that there is a robust system of reporting adverse incidents or serious untoward incidents, that all incidents are documented, investigated and followed up with appropriate action and that any lessons learnt from incidents are shared across the organisation and with the commissioners

The service should be available during the practices contracted hours (i.e. 8.00am to 6.30pm) for 52 weeks of the year, subject to sample collection services, and evidence should be provided that appropriate plans have been devised for cover of leave (both anticipated and unanticipated) and succession planning for staff turnover.

The provider will have plans and procedures in place to provide the service if there are any unforeseen closures or breaks in service such as power cuts, floods etc. The practice must notify the PCT of any such incidents.

Performance Monitoring and Audit Arrangements

The Provider must ensure an appropriate record of activity is developed and maintained for audit and payment purposes and which meets the requirements of this contract.
The provider shall provide quarterly activity data to NHS Dorset in respect of this service during the year using the electronic monitoring return provided. Activity data will include the number of patients on the register on the last day of each quarter.
The provider is encouraged to undertake quarterly audit/clinical review of the care provided. As a minimum, the provider will report the results of an audit of the service annually. The results will be reported to the PCT. The report will include,

as a minimum:
compliance with monitoring regimes
complications, untoward incidents and significant events including never events

The contractor must inform NHS Dorset, at the earliest opportunity, if there is a significant disruption to the service in order that continuity can be maintained through an alternative provider.

Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

It is a condition of participation in this service that practitioners will give notification, in addition to their statutory obligation, within 72 hours of the information becoming known to him/her, to the PCT Clinical Governance Lead, of all emergency admissions or death of any patient covered under this service, where such admission or death is, or may be due, to usage of the drug(s) in question or attributable to the relevant underlying medical condition.

5.2 Applicable CQUIN goals (See Schedule 4 Part E)

N/A

Location of Provider Premises

The Provider's Premises are located at:

Individual Service User Placement