NHS
Somerset
Clinical Commissioning Group

Service Specification No.	11X-04 V2
Service	Enhanced Drug Monitoring
Commissioner Lead	As per the Particulars of the NHS Standard Contract
Provider Lead	As per the Particulars of the NHS Standard Contract
Period	1 April 2021 – 31 March 2024
Date of Review	October 2021

1. Population Needs

National/local context and evidence base

1.1 The treatment of several diseases within the fields of medicine, such as rheumatology and atrial fibrillation, is increasingly reliant on drugs that, while clinically effective, need regular blood 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 can be reduced significantly if this monitoring is carried out in a well organised way, close to the Service User's home.

1.2 Recently, the British Society of Rheumatologists has revised its guidance for the monitoring of immunomodulatory therapies to standardise and simplify the monitoring for these drugs. Appendix 1 in this specification provides the individual drug monitoring requirements which are being commissioned. It also includes guidance on the drug monitoring requirement for Dronedarone, used to prevent recurrence of atrial fibrillation, or to lower ventricular rate.

1.3 Providers should note that the individual drugs Summary of Product Characteristics (SPC) may specify more intense drug monitoring than this enhanced service specification. The level of monitoring commissioned has been set upon what is deemed safe and practical for the overwhelming majority of Service Users prescribed one of the drugs specified.

1.4 Prescribers are recommended to take into account the individual Service Users co-morbidities and co-prescribed medication when deciding whether to monitor Service Users more frequently than set out in the enhanced service. Particular consideration should be given to increased monitoring in Service Users newly initiated, after a dose increase, with impaired renal function or on combinations of two drugs in the enhanced service or another drug likely to increase the need for monitoring

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 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

Not applicable

3. Scope

Aims and objectives of service

SERVICE AIMS

3.1 The Enhanced Drug Monitoring Service is designed to be one in which:

- therapy is only started for recognised indications and for specified lengths of time
- maintenance of Service Users who have not first been stabilised in the secondary care setting can be under taken safely in primary care with a shared care approach between consultant and GP.
- the service to the Service User is convenient
- the need for continuation of therapy is reviewed regularly
- the therapy is discontinued when appropriate, including discussing any reported side-effects with the relevant secondary care department (e.g. rheumatology) if necessary
- any necessary monitoring is undertaken as commissioned, the GP gives due consideration to additional monitoring if recommended by the secondary care consultant or is clinically indicated, and
- the use of resources by the National Health Service is efficient.

Service description/care pathway

3.2 The Enhanced Drug Monitoring service shall include the provision of the following specified drugs:

Immunomodulatory therapies

- Sulfasalazine
- Azathioprine
- Penicillamine
- Leflunomide
- Oral Methotrexate
- Sodium Aurothiomalate (Myocrisin)
- Sub-cutaneous Methotrexate injections
- Hydroxychloroquine
- Mercaptopurine

Other Drugs

- Dronedarone

3.3 Services not included in specification

- Monitoring of drugs not listed above such as chlorambucil, ciclosporin, etanercept, infliximab or other biological drugs.

SERVICE REQUIREMENTS

3.4 The Provider shall ensure that the Enhanced Drug Monitoring Service includes but is not limited to:

3.5 Service specification and criteria

- ensuring that all newly diagnosed Service Users (and/or their carers and support staff when appropriate) receive appropriate education and advice on management, and prevention of, secondary complications of their condition, including the provision of written information
- ensuring that the systematic call and recall of Service Users is taking place
- ensuring that all Service Users (and/or their carers and support staff when appropriate) are informed of how to access appropriate and relevant information
- preparing an individual management plan with the Service User, which gives the diagnosis, planned duration, the monitoring timetable and, if appropriate, the therapeutic range to be obtained
- referring Service Users promptly to other necessary services and to the relevant support agencies, when clinically appropriate, using locally agreed shared care guidelines, link provided in 3.24, where these exist and in line with any Summary of Product Characteristics datasheets available at www.medicines.org.uk
- working with other professionals when appropriate
- developing and maintaining an up-to-date register of all Service Users , indicating Service User name, date of birth, the indication for treatment, duration of treatment and last hospital appointment
- maintaining adequate records of the performance and results, incorporating appropriate known information. This shall include all known information relating to any significant events e.g. hospital admissions and death of which the provider has been notified.
- Community nursing services staff are only able to take samples for those housebound Service Users already on their caseload.
- Any blood tests results obtained under this specification must be added to the patient practice record

Quality Assurance

3.6 The Provider acknowledges that:

- quality assurance must be carried out in accordance with relevant local and national guidance and protocols
- Practitioners delivering the service are aware and have access to copies of the latest shared care protocols. A link to the protocols can be found in 3.24

Health Record

3.7 The Provider should ensure that all clinical information related to this service is recorded in the Service User's own General Practitioner (GP) held lifelong record.

3.8 Where a Service User ceases to take drugs that are relevant to this service then the Service User record should be duly updated.

Training and Accreditation

3.9 The Provider shall ensure that:

- all staff providing any aspect of care under Service have the necessary training and skills to do so; the expertise of other professionals can be drawn on where necessary
- all staff involved in this service should be providing care in accordance with the shared care protocols, link provided in 3.24.

INFECTION CONTROL

3.10 Providers must have infection control policies that are compliant with national guidelines and current handling protocols, including, but not limited to The Health and Social Care Act 2008 Hygiene Code (refer to 3.25) and which takes into account:

- disposal of clinical waste
- needle stick incidents
- environmental cleanliness
- standard precautions, including hand washing
- Reference to lone worker policy especially for Domiciliary visits

SIGNIFICANT/ADVERSE EVENTS

3.11 The Department of Health emphasizes the importance of incidents collated nationally to ensure that lessons are learned across the NHS. A proactive approach to the prevention of recurrence is fundamental to making improvements in Service User safety.

3.12 The Provider should be aware of (and use as appropriate) the various reporting systems such as:

- The National Reporting and Learning System (NRLS). Reports to NRLS can be submitted electronically via the General Practice Patient Safely Incident report Form, or the national GP e-form. If using the GP e-form please check the box to share your report with Somerset CCG.
- the Medicines and Healthcare products Regulatory Agency reporting systems for adverse reactions to medication (yellow card system), and accidents involving medical devices, and
- the legal obligation to report certain incidents to the Health and Safety Executive under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR).

3.13 In addition to their statutory obligations, the Provider will notify the Commissioner within 72 hours of being aware of the hospital admission or death of a patient being treated by the Provider under this enhanced 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 via the email address below

3.14 In addition to any regulatory requirements the CCG wishes the Provider to use a Significant Event Audit system (agreed with the Clinical Commissioning Group) to facilitate the dissemination of learning, minimising risk and improving patient care and safety. Providers shall:

- Report all significant events to the CCG within 2 working days of being brought to the attention of the Provider via somccg.significantevents@nhs.net

- Undertake a significant event audit (SEA) using a tool approved by the CCG and forward the completed SEA report to the CCG within one month of the event via https://www.somersetccg.nhs.uk/for-clinicians/general-practice-significant-event-sea-and-serious-incident-support/

REVIEW AND AUDIT

3.15 The Provider shall confirm quarterly that::

- Rheumatology and Dermatology patients starting treatment or after dose increase should receive FBC, Creatinine, LFT and Albumin tests/monitoring:

  Every 2 weeks until stable for 6 weeks then every month for 3 months.

- Gastroenterology patients starting treatment or after dose increase should receive FBC, Creatinine, LFT and Albumin tests/monitoring:

  Every 2 weeks until stable for 8 weeks, repeat again in another 4 weeks then maintenance monitoring every 12 weeks.

3.16 Practices will confirm the number of patients and test conducted for each quarter. The CCG may check this information against the data on Eclipse to ensure safety of service delivery. Should there be any variation, the CCG may ask for further information, as the CCG are aware that patients may be monitored elsewhere, or not agreed to their data being shared. If the practice is aware of this, practices should include this detail in their return.

3.17 Practices will confirm through data, that all patients have been monitored as per the specification.

PAYMENT

3.18 This service is subject to a local price, which is set out in Schedule 3 Part A.

3.19 Where a Service User is receiving combinations of two or more drugs covered by this specification, only one payment per Service User will be made.

CONSENT

3.20 The patient should be fully informed of the treatment options, risk and the treatment being proposed, consented and willing to participate.

SERVICE USER AND PUBLIC INVOLVEMENT

3.21 Patients should be involved in the decisions about their care and given high-quality information to enable them to make fully informed decisions regarding their ongoing care.

3.22 The Provider should encourage, consider and report any Service User feedback (positive and negative) and use it to improve the care provided to Service Users, particularly if there are plans to alter the way a service is delivered or accessed.

REFERENCES

3.23 Individual drugs SPCs www.medicines.org.uk .

3.24 Somerset Shared Care protocols: https://www.somersetccg.nhs.uk/prescribing-and-medicines-management/shared-care/

3.25	The Health and Social Care Act 2008: Code of practice on the prevention and control of infection and related guidance. https://www.gov.uk/government/publications/the-health-and-social-care-act-2008-code-of-practice-on-the-prevention-and-control-of-infections-and-related-guidance
	Population covered
3.26	The service will be available to patients registered at a Somerset GP practice.
	Any acceptance and exclusion criteria and thresholds
3.27	Patients whose care is not suitable for primary care management are excluded from this service.
	Interdependence with other services/providers
3.28	In providing this service, Providers will be required to work closely with secondary care Providers.

4. Applicable Service Standards

4.1 **Applicable national standards (e.g. NICE)**

4.2 **Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)**

Not applicable

4.3 **Applicable local standards**

Not applicable

5. Applicable quality requirements

5.1 Applicable quality requirements (See Schedule 4 Parts A&C)

6. Location of Provider Premises

6.1 **The Provider's Premises are located at:**

As per the Particulars of the NHS Standard Contract

APPENDIX 1

Revised guidance around the monitoring immunomodulatory therapies to standardise and simplify the monitoring for these drugs. Please follow the below link for the individual drug monitoring requirements which are being commissioned. Practices will be required to follow the guidance for Immunomodulatory therapies in rheumatology/gastroenterology and dermatology conditions -DMARDS and Dronedarone.

https://www.somersetccg.nhs.uk/prescribing-and-medicines-management/shared-care/

~~N.B – On page 15 of the Shared Care Guidance for 'Immunomodulatory therapies in rheumatology/gastroenterology and dermatology conditions –DMARDS' the 'other monitoring requirement' for Hydroxychloroquine should not be followed.~~

~~The current monitoring requirement requires the following:~~

- ~~Annual eye assessment (ideally inc. Optical Coherence Tomography if continued for > 5 years arranged in secondary care).'~~

~~However the CCG currently does not have any commissioning arrangements in place to accommodate this requirement and as such practices are asked to revert back to the previous guidance which states:~~

- ~~Annual review by an optometrist. The examination should include testing visual acuity, careful ophthalmoscopy, fundoscopy, central visual field testing with a red target, and colour vision. Discuss with the ophthalmologist if on treatment for >5years~~

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