

Service Specification

Service Specification No.	
Service	Safe prescribing of medicines locally commissioned service
Commissioner Lead	NHS Shropshire CCG and NHS Telford and Wrekin CCG
Provider Lead	
Period	01/09/2020-31/03/2021
Date of Review	January 2021

1. Population Needs

1.1 Background

Within NHS Shropshire CCG and Telford & Wrekin CCG, the Shropshire and Telford Local Health Economy formulary classifies medicines as Red/Amber/Green/Black to clarify which medicines GPs could reasonably be asked to prescribe, and which medicines should remain the responsibility of hospital specialists. Medicines listed as amber are considered suitable for prescribing in Primary Care following specialist (consultant or GPwSI) initiation or recommendation. Specialist initiation or recommendation is often required because of complex assessment and diagnostic criteria of the disease being treated. Some of these medicines may require on-going communication between the specialist and the Primary Care prescriber using Prescribing Information (PI) or through the use of an Effective Shared Care Agreement (ESCA); this will be clearly indicated on the local health economy formulary. The local health economy formulary can be accessed here:

<http://www.shropshireandtelfordformulary.nhs.uk>

For medicines requiring an ESCA it is considered reasonable to request transfer of prescribing responsibility after an agreed period of time. Prescribing responsibility is normally transferred between 2 and 4 months after initiation, providing the medicine has been shown to be tolerated. However, the hospital specialist will still follow-up the patient at least annually and more frequently if clinically necessary. Any GP who prescribes medication legally assumes responsibility for the drug and the consequences of its use. Prescribers have a duty to keep themselves informed about the medicines they prescribe, their appropriateness, effectiveness and cost. They should keep up to date with the relevant guidance on the use of the medicines and on the management of the patient's condition.

The management of various clinical conditions within the fields of medicines rely on prescribing of medicines that while clinically effective, require regular monitoring. This is due to the potentially serious side effects that these drugs can occasionally cause, and regular monitoring can reduce the incidence of these occurring. Some medicines also need greater discussion with the patient when they are initiated.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 2	Enhancing quality of life for people with long-term conditions	x
Domain 3	Helping people to recover from episodes of ill-health or following injury	x
Domain 4	Ensuring people have a positive experience of care	x
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	x

2.2 Local defined outcomes

This service provides funding for practices within Shropshire and Telford to manage systems for initiation, where clinically appropriate, and an ongoing enhanced level of monitoring of prescribed medicines. The funding is for medicines that require ongoing review/ monitoring over and above what would be expected as part of standard care.

3. Scope

3.1 Aims and objectives of service

This service covers medicines initiated in secondary care and recommended for continuation in primary care under guidance or shared care; and medicines initiated in primary care. The medicines currently covered under this service are listed in Appendix One. Where medicines are initiated or recommended by secondary care this should be in line with shared care or prescribing information guidance that has been approved by Shropshire and Telford Local Health Economy Area Prescribing Committee (APC) which includes GP representation. Appropriate communication between secondary and primary care is required.

Appendix one will be regularly reviewed throughout the year as needed at the time of change, to consider any in year changes to medicines with APC approved ESCA or prescribing information, in order to determine whether any medicines should be added or removed from the agreed list. Only medicines with APC approved ESCA or prescribing information documents will be added to Appendix one medicines list.

For new medicines with significant workload or commissioning implications that warrant additional investment in Primary Care or new commissioning arrangements over and above the allocated funding for this scheme, these will be reviewed via the CCG's commissioning processes and the Local Medical Council (LMC) will be consulted prior to their inclusion.

An enhanced monitoring of medicines service is designed to:

- i. Include therapy initiated in primary care or secondary care for appropriate clinical indications.
- ii. Provide a primary care service so patients have access to local and convenient

- service without the need for hospital visits.
- iii. Ensure patients receive a safe and appropriate level of care.
- iv. Ensure national and local guidance and standards are followed.
- v. Optimise the use of NHS resources.

3.2 Service description

Shropshire CCG and Telford and Wrekin CCG will fund the practices to provide initiation and/or an enhanced monitoring and management of medicines service in primary care.

3.2.1 Develop and maintain a register. Providers should be able to produce an up-to-date register of all patients on the medicines included using a specified Read code. Patients taking warfarin who are managed (dosed) by another provider should be coded.

Read Codes:

EMIS 9kD, SNOmed: 166381000000102 Near patient testing – enhanced service administration

For patients on warfarin who are monitored by another provider the following Read codes should be used:

EMIS 66QC SNOmed: 199761000000102 Anticoagulation monitoring – secondary care

EMIS 66QD SNOmed: 279231000000108 Anticoagulation monitoring – primary care

EMIS 66QE SNOmed: 309901000000107 Self-testing of INR

EMIS 8BM5 SNOmed: 415522008 Shared Care Prescribing

3.2.2 Call and recall. Providers should ensure that a systematic call and recall system is in place and should be able to demonstrate the effectiveness of the system. Under normal circumstances, a patient who fails to attend a clinic or for monitoring tests at an agreed time should be contacted initially by telephone. Where a patient fails to attend, consideration should be given as to whether it is safe to continue prescribing the medicine until the patient is seen or test results received.

3.2.3 Safety systems and process

Practices should implement systems and processes to enable them to identify and manage patients at risk of Hospital Admissions Related to Medicines (HARMS) or serious adverse events from medicines. The CCG recommends the use of PINCER and/or ECLIPSE to support this. CCG support can be provided to implement these software systems and suggest best practice approaches to utilising these systems as a tool to support the identification of high risk patients.

3.2.4 Professional links and communication. Where the service is not provided by the patient's GP practice, the service provider and the patient's GP have a shared responsibility for ensuring a robust communication system is in place.

3.2.5 Referral policies. Providers should, when appropriate, refer patients promptly to other necessary services and to the relevant support agencies using locally agreed guidelines where these exist.

3.2.6 Training and Quality and Safety Requirements. Service providers must ensure they have sufficient workforce capacity, capability and sustainability to ensure effective service delivery. This should include contingency plans to cover periods of absence for annual leave or sickness. All staff/ health professionals involved in providing any aspect of care under this scheme must have the necessary training and skills to do so for the elements of the service that they provide.

3.2.7	Provision of adequate facilities including premises. All premises providing any aspect of this service must have adequate equipment and protocols including standard operating procedures in place.
3.2.8	Annual review. Providers should be able to provide the following information to the CCG when requested: <ul style="list-style-type: none"> • Details of training and education relevant to the drug monitoring service. • Details of the standards used for the control of the relevant condition. • Assurance that any staff member responsible for prescribing has developed the necessary skills to prescribe safely • Details of the call/recall system • Details of any computer-assisted decision-making equipment used and arrangements for internal and external quality assurance (where applicable). • Details of any near- patient testing equipment used and arrangements for internal and external quality assurance (where applicable).
3.3	Care Pathway
3.3.1	Education and newly diagnosed patients. The initiating clinician should ensure that all newly diagnosed/ treated patients (and/ or their carers and support staff when appropriate) receive appropriate education and advice on the management of their condition and any secondary complications that may arise. This should include written information where appropriate and for warfarin should include the hand held 'Yellow Book' or equivalent anticoagulation record.
3.3.2	Continuing information for patients. To ensure that all patients (and/ or their carers and support staff when appropriate) are informed of how to access appropriate and relevant information.
3.3.3	Individual management plan. The initiating clinician should ensure the patient has an individual management plan where appropriate which gives the reason for the treatment, the planned duration, the monitoring timetable and, if appropriate the therapeutic range to be obtained
3.3.4	Prescribing The prescription of the medication is the responsibility of the patient's GP and includes any dose changes required as a result of monitoring unless dosing is being undertaken by a provider other than the GP practice (e.g. ongoing warfarin dosing by Secondary Care Anticoagulation clinic). In this case decisions on dosing will be the clinical responsibility of the Secondary Care provider. Practices should have standard operating procedures in place to cover all aspects of high risk drug prescribing and VKA anticoagulant prescribing. Where practices are prescribing test strips for patient INR testing equipment, practices need to ensure they have received documentation from Secondary Care Anticoagulation Services as an assurance that the patient's INR testing equipment is having regular quality control checks.
3.3.5	Monitoring It is important for the prescriber to check the patient is being monitored regularly in line with ESCA, prescribing information document or product recommendations where ESCA or PID are not required, and that it is safe for a repeat prescription to be issued (e.g. INR regularly being monitored for warfarin). In some cases it may be appropriate and some patients may choose to self-monitor (e.g. INR monitoring, blood pressure monitoring etc) this will involve the patient performing their own test at home using a point of care device. The practice

or Secondary Care provider can decide which patients may be suitable for self-monitoring of their INR. Where it is deemed appropriate for patients to self-monitor this should be done in line with the Secondary Care Anticoagulation clinic agreement and patients should receive the relevant and necessary training.

- 3.3.6 **Individual annual review** Service providers will be required to conduct a formal review of the patient's health in relation to their medicine(s) at least annually, including review of continued need for treatment where this aspect of treatment is being managed by primary care. This review should be conducted and clearly documented in the patient's clinical record.

Where patients are managed under a shared care arrangement, Primary Care service providers should confirm the patient has attended secondary care for review as appropriate; and take any necessary action if the patient did not attend to ensure on going safe prescribing.

- 3.3.7 **Record- keeping.** Providers should maintain adequate records of the performance and results 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.

- 3.3.8 **Incidents/Serous Incidents** The Primary Care provider is required to have a robust incident management policy in place covering the recognition and management of all incidents. This must include data collection mechanisms, formal risk assessment, action planning and shared learning.

It is a requirement that any incident that results in significant harm to a patient including medication, equipment or serious communication failure within this service is notified to the CCG Quality Team as per the providers internal serious incident policy.

All serious incidents must be reported and submitted within timescales (within 2 working days) laid out within the National SI Framework to the CCGs Quality Team, so that these incidents can be reported on the providers behalf by the CCG onto the National reporting system.

A Root Cause Analysis (RCA) investigation of the serious incident should be completed and investigation report should be shared with the CCG Quality Team within the agreed national timeframes.

The provider shall also inform the CCG Medicines Management Team of any drug related incidents (e.g. interacting medicine causing adverse changes to blood results, delayed or missed monitoring of blood results, treatment continued inappropriately etc.)

- 3.3.9 **Point of care testing and quality control** If Point of Care Testing (POCT) is used, service providers will pay for all POCT equipment and supplies including the test strips, finger prick equipment, external quality assurance and internal quality control requirements unless agreed otherwise by the relevant CCG. The POCT equipment must be maintained and calibrated as per the manufacturer's guidance and recorded. It is good practice to be able to track the time of testing and lot number of test strip used for each patient should the need arise. Cleaning procedures recommended by the manufacturer should be adhered to and health and safety standards should be followed at all times.

The disposal of sharps should be in accordance with national guidance and the provider's waste disposal and infection control policy.

Service providers will be expected to have the required external quality assurance (EQA) and internal quality control (IQC) systems in place.

3.3.10 Risk management Practices should have a risk management strategy in place to deal with patients that are experiencing adverse effects relating to their medicines (e.g. timely access to vitamin K for patients with bleeding or raised INRs).

3.4 Population covered

This service applies to all patients registered with a Shropshire or Telford GP practice taking any of the medicines covered by this service specification unless agreed with the secondary care provider that the patient should be managed entirely by them including prescribing responsibility.

3.5 Any acceptance and exclusion criteria and thresholds

None

3.6 Interdependence with other services/providers

This service should be delivered as part of a seamless service for patients. Where the service provider is not the patients' GP, they should ensure robust communication mechanisms are in place.

4. Applicable Service Standards

4.1 Applicable national standards (eg NICE)

Compliance with relevant guidance and policy

The service must comply with the guidelines produced by the following organisations (where applicable):

NICE Guidance and recommended pathways <http://guidance.nice.org.uk/>

Care Quality Commission registration requirements.

UKMI Suggestions for Drug Monitoring in Adults in Primary Care (February 2014)

NHS Telford & Wrekin and Shropshire CCG Shared Care Agreements

NPSA Actions that can make anticoagulant therapy safer ref: NPSA/2007/18
<http://www.nrls.npsa.nhs.uk/resources/?entryid45=59814>

NICE CG 180: Atrial Fibrillation <https://www.nice.org.uk/guidance/cg180>

Shrewsbury and Telford Hospital NHS Trust local guidelines

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

Rules of Professional Conduct

<http://www.gmc-uk.org/guidance/index.asp>

4.3 Applicable local standards

Applicable policies produced by NHS Telford & Wrekin and Shropshire CCGs and any adaptations to these policies as adopted from the 1st April 2020 including Area Prescribing Committee guidance:

4.4 Equal Opportunities

The service provider must demonstrate how they meet equal opportunity requirements in the following areas:

- They must be committed to equal opportunities and must not discriminate in performance of the service towards service users or members of staff in any way;
- The service provider must be able to provide chaperones at the patient's request;
- The service provider must also be able to provide premises, facilities and treatment rooms that are compliant with disability legislation
- The service provider must be able to provide access to foreign language interpreter if necessary.

4.5 Clinical qualifications

Staff involved in the delivery of this service will be appropriately trained and competent in the provision of the services offered.

The services provided and scope of these services will be reviewed with staff as part of the annual appraisal process

The service provider must provide evidence to the CCGs that their healthcare professionals have the appropriate knowledge, skills, experience, qualifications and competency to provide the service. This must include but would not be limited to the following requirements:

- Enhanced Disclosure and Barring Service (DBS formally Criminal Records Bureau CRB) checks have been completed;
- Where applicable staff will be fully registered with the appropriate Professional Body;
- All staff will be able to provide evidence of their continuing professional development post qualification.

The service provider must comply with all relevant policies and procedures as contained in the NHS Standard Contract including but not limited to; safeguarding of vulnerable

patients (including children), health and safety, marketing and branding and insurance requirements (professional, public and product and employer's liability).

The service provider must also comply with all relevant guidance and referral protocols produced by the CCG. The aim of these protocols will be to ensure that patients are treated by the most appropriate professional, in the most appropriate location with the most effective treatment.

4.6 Clinical Governance

The service provider will be responsible for establishing robust internal clinical governance structure with an internal Clinical Governance Lead who is responsible for assuring the clinical quality of the service and that it is supported by a suite of robust operational and clinical policies and procedures. This will include but not be limited to the following:

- An appointed provider Clinical Governance Lead;
- Development and implementation of internal provider Clinical Governance policies.
- Adhering to applicable General and service conditions within the NHS contract.

4.7 Patient Transport

Patient transport arrangements do not form part of this service specification. Patients will be expected to make their own transport arrangements. Those patients who are entitled to assistance with transport under existing NHS arrangements will be able to access this through their GP Practice as per local arrangements.

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements

National quality requirements in line with Schedule 4 parts A-D of standard NHS contract

5.2 Applicable CQUIN goals

There are no CQUINS for this service

6. Location of Provider Premises

Within the GP practice or other appropriate room in the Primary Care Network area.

7. Payment

The Safe Prescribing of Medicines LCS will be run as a shadow scheme in year from 1st September 2020, with guaranteed income to practices at 2019/20 levels.

Fees under the contract will cover all costs associated with the service i.e. strips, external/internal calibration, software and hardware unless otherwise agreed.

A list of the medicines included in this service is given in Appendix One. This list is subject to review throughout the year. New medicines with APC approved ESCA or prescribing information will be considered to determine whether they should be added or removed from the agreed list. For new medicines with significant workload or commissioning implications that warrant additional investment in Primary Care or new commissioning arrangements over and above the allocated funding for this scheme, these will be reviewed via the CCG's commissioning processes and the Local Medical Council (LMC) will be consulted prior to their inclusion.

When assessing the appropriate level of funding the CCG will benchmark against existing medicines, considering the type of monitoring required and the frequency. Prescribing of agreed new medicines will be expected in primary care and the scheme will be assessed in year to determine whether any medicines should be added or removed from the agreed list.

9. Key Performance Indicators and Quality Requirements

9.1 Key performance indicators

For each of the measures providers will be expected to report quarterly

Key Performance Indicators	Description	CCG Monitoring
100% of medicines safety incidents should be reported via Ulyses. Incidents meeting the Serious Incident criteria must be reported to the CCGs within 2 working days.	The provider actively uses the Ulyses system to report all medicines errors and near misses to enable learning across the whole health system. The provider should aim to report all serious incidents to the CCGs within 2 working days.	It is expected that all practices will have increased reporting rates. Ulyses reporting rates will be monitored. Practices with unusually high or low reporting rates will be supported to review their systems.
100% of patients on these drugs have the correct Read Code for the drug indication	The provider must work to ensure that all patients on these drugs have the correct read code for the drug indication recorded on the patient's clinical history.	Quarterly EMIS searches
90% of patients on these drugs have monitoring undertaken (as indicated within the appropriate guidelines) prior to issue of prescriptions.	The provider must demonstrate that at least 90% of patients on these drugs have monitoring undertaken in accordance with the shared care guidelines and that prescriptions are issued following satisfactory results of monitoring.	Quarterly EMIS searches, practice audit (e.g. warfarin-see CCG anticoagulation guidance), PINCER and ECLIPSE data. Where this is not being achieved, the CCG expects practices to demonstrate systems in place to safety net and follow these patients up
100% of patients have a recall set up in the GP clinical system specifically for drug monitoring including identifying when patients have their follow up hospital appointment recorded (where applicable for patients under shared care with a specialist) and identifying any patients that DNA.	Practices must have a robust call and recall system in order to identify patients that have not had appropriate reviews in line with the ESCA, PID or product recommendations. Practices should follow the advice in the ESCA/PID in the event of patients not attending clinical review or having the required safety monitoring.	Practices should provide detail of their systems for call and recall of patients prescribed high risk drugs.

<p>100% of patients have a record of advice and information regarding their condition and drug therapy and monitoring requirements having been given.</p>	<p>The provider must demonstrate that 100% of patients on these drugs have a record of advice and information regarding their condition and drug therapy being given, this may be recorded directly on to the GP clinical system or contained within the ESCA documentation (as applicable for medicines that require ESCA).</p>	<p>Practice may be requested to provide a sample audit to demonstrate this.</p>
<p>Practices should demonstrate their systems and processes used to identify and manage patients at risk of Hospital Admissions Related to Medicines (HARMS) or serious adverse events from medicines.</p>	<p>The provider must demonstrate they have robust systems/tools in place to identify and prioritise patients at risk of adverse effects from medicines or hospital admissions for review. This can be demonstrated by practices having and actively utilising medicine safety systems e.g. PINCER and/or ECLIPSE The provider must have an identified responsible lead for medicine safety systems and processes within the practice.</p>	<p>Practices to submit their process within Q1 and provide name of medicines safety lead. CCG to monitor use of PINCER and ECLIPSE where practices have this in place.</p>

Appendix One: Drugs included in the service specification

Medication	Indication	Documentation
Methylphenidate	ADHD	ESCA
Dexamfetamine	ADHD	ESCA
Lisdexamfetamine	ADHD	ESCA
Guanfacine	ADHD	ESCA
Atomoxetine	ADHD	ESCA
Fluoxetine	CAMHS- Depression	ESCA
Risperidone	CAMHS-Conduct disorder	ESCA
Somatropin	Growth Hormone deficiency	ESCA
Warfarin	Anticoagulation	N/A
Apixaban	Anticoagulation	N/A
Dabigatran	Anticoagulation	N/A
Edoxaban	Anticoagulation	N/A
Rivaroxaban	Anticoagulation	N/A
Tinzaparin	Sub-therapeutic INR, DVT bridging, VTE in cancer	N/A
Enoxaparin	Sub-therapeutic INR, DVT bridging, VTE in cancer	N/A
Amiodarone	Cardiac rhythm disorders in adults	ESCA
Dronedarone	Non-Permanent Atrial Fibrillation (AF)	ESCA
Sacubutril/Valsartan	Heart failure once stabilised	PID
Rivastigmine	Dementia	ESCA
Galantamine	Dementia	ESCA
Memantine	Dementia	ESCA
Donepezil	Dementia	ESCA
Denosumab	Osteoporosis	ESCA
Azathioprine	DMARDs for all licensed indications	ESCA
Ciclosporin	DMARDs	ESCA
Dapsone	DMARDs	ESCA
5-Aminosalicylates – Balsalazide, Mesalazine and Olsalazine	DMARDs	ESCA
Penicillamine	DMARDs	ESCA
Hydroxycarbamide	DMARDs	ESCA
Leflunomide	DMARDs	ESCA
Mercaptopurine	DMARDs	ESCA
Methotrexate	DMARDs	ESCA
Mycophenolate mofetil	DMARDs	ESCA
Sulfasalazine	DMARDs	ESCA
Tacrolimus	DMARDs	ESCA
Lithium	MH	ESCA
Antipsychotics*	Schizophrenia, bipolar disorder	ESCA
Sodium Valproate for women of child bearing age	For all licensed indications	ESCA
Brivaracetam	Epilepsy	
Riluzole	Motor Neurone Disease	
Apomorphine	Parkinson's Disease	