

SCHEDULE 2 – THE SERVICES

A. Service Specification

Service Specification No	
Service	Near Patient Testing
Commissioner Lead	Sarah Boyd-Short, Commissioning Lead – Primary Care, Wirral Health & Care Commissioning
Provider Lead	GP Practices
Period	1 April 2019 – 31 March 2021 (2 years)
Date of Review	Circa July 2019 and December 2020

1. Population Needs

1.1 National/Local Context and Evidence Base

The treatment of several diseases within the fields of medicine, particularly in rheumatology, 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 patient's home.

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

- High quality personalised care
- Monitoring closer to home
- Reduction in side effects from specific medicines
- Reduction in secondary care attendances/admissions
- Improved patient satisfaction

3. Scope

3.1 Aims and Objectives of the Service

The service is designed to be one in which:

- (i) therapy should only be started for recognised indications for specified lengths of time
- (ii) maintenance of patients first stabilised in the secondary care setting should be properly controlled

- (iii) the service to the patient is convenient
- (iv) the need for continuation of therapy is reviewed regularly
- (v) the therapy is discontinued when appropriate
- (vi) the use of resources by the National Health Service is efficient.

3.2 Service Delivery

3.2.1 Requirements

To provide a shared care drug monitoring service in respect of the following specified drugs:

- (a) Penicillamine
- (b) Auranofin
- (c) Sulphasalazine
- (d) Methotrexate (including for the treatment of Sarcoidosis and Asthma)
- (e) Sodium Aurothiomalate.
- (f) Leflunamide
- (g) Azathioprine
- (h) Ciclosporin
- (i) Mycophenylate mofetil
- (k) Denosumab injections
- (f) This could also cover all 'amber' lists drugs where shared care is appropriate as agreed between the participating practices and NHS Wirral Clinical Commissioning Group (CCG)

A shared care condition monitoring service of stable Monoclonal Gammopathy of Undetermined Significance (MGUS) and stable Chronic Lymphocytic Leukaemia (CLL). In addition, the administration of Denosumab injections for the treatment of osteoporosis in postmenopausal women at increased risk of fractures.

Patients with MGUS require follow up every 3 - 4 months for first year and then every 6 - 12 months thereafter for life, although if there has been no significant change over 12 months, the monitoring interval can be extended to 6 monthly and then 12 monthly as clinically appropriate.

Patients with CLL require follow up every 4 -6 months for life.

3.2.2 Denosumab injections

Patients on Denosumab will receive the recommended dose of 60mg administered as a single subcutaneous injection once every 6 months for a period of up to 3 years. Patients must be adequately supplemented with calcium and vitamin D. The GP must ensure other osteoporosis treatments are removed from the patient's prescription. Upon completion of treatment, or sooner if any concerns occur, the GP must refer patient back to the consultant for review. See Appendix 5.

Suitable patients will be discharged, to this service, from their Out Patients Department appointment.

3.2.3 Register

The provider must maintain an up-to-date register of all shared care drug and condition monitoring service patients, indicating patient name, date of birth and the indication and duration of treatment.

3.2.4 Call and Recall

The provider will ensure that systematic call and recall of patients on the registers takes place.

3.2.5 Continuing information for patients

The provider will ensure that all patients (and/or their carers and support staff when appropriate) are informed of how to access appropriate and relevant information. The service will be fully inclusive of all patients, communities and cultures and will provide appropriate assistance and make reasonable adjustments for patients and carers in particular where; English is not their first language, those who have communication difficulties and those with cognitive, emotional and physical impairments.

3.2.6 Individual Management Plans

The provider will ensure that all patients have individual management plans, which gives the reason for treatment, the planned duration, the monitoring timetable, the therapeutic examination undertaken and, where appropriate, the therapeutic range to be obtained.

The management plan must follow recognised care pathways (including Map of Medicine where available), ensure appropriate blood tests are reviewed and acted upon and appropriate clinical examinations are conducted and documented.

3.2.7 Professional Links

The provider will work with other professionals when appropriate. Any health professionals involved in the care of patients in the programme should be appropriately trained.

3.2.8 Referral Policies

The provider, where appropriate, will refer patients promptly to other necessary services and to the relevant support agencies using locally agreed guidelines where these exist.

3.2.9 Record Keeping

The provider agrees to 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.

3.2.10 Staffing

The provider must ensure that all staff are trained and competent to deliver a high quality and safe service under this scheme. The practice will ensure that all staff can demonstrate the relevant qualifications, competencies, training and supervision as necessary to enable them to deliver the service to a high standard.

3.2.11 Annual Review

All provider involved in the scheme should perform an annual review of their patients and allow the NHS Wirral CCG access to their information system to extract data using a MIQUEST / Graphnet query to audit activity.

3.2.12 Education and Newly Diagnosed Patients

Wirral University Hospitals Trust (WUTH) will ensure that all advice on management of and prevention of secondary complications of an individual's condition is provided on initiation of therapy. This should include written information where appropriate.

3.2.13 Training / Guidelines

MHS Wirral CCG will organise educational and training events for practices and provide clinical guidelines/ protocols for management of these patients where required.

3.3 Care Pathway

See the following Appendices:

Appendix 1 – Map of Medicine Care Pathway for MGUS

Appendix 2 – Map of Medicine Care Pathway for CLL

Appendix 5 – Use of Denosumab

3.4 Relevant Networks and Screening Programmes

Where appropriate the provider will participate in relevant local and national network and applicable

programmes to inform and support the development of national and local policies.

3.5 Acceptance Criteria

All patients registered with a Wirral GP receiving the listed medications and suitable for management within Primary Care.

3.6 Exclusion Criteria

Patients not in receipt of the listed medications.
Patients not registered with a Wirral GP.

3.7 Interdependence with other Services/Providers

The provider will collaborate with current and prospective partners and stakeholders such as GP practices to provide a local and sustainable service for the best interest of patients. The practice will work closely with WH&CC to address any issues which may arise. The practice will work with partners to deliver safe and effective pathways of care. Partners will include, but not limited to;

- Wirral GP practices
- Wirral University Teaching Hospital (WUTH)
- Wirral Community NHS Trust (WCT)
- Cheshire and Wirral Partnership NHS Foundation Trust (CWP)
- Patients and patient groups
- Other providers of NHS services

3.8 Information Management and Data Protection

All providers and commissioners must manage service user identifiable data in accordance with the law and established good practice in health and social care settings. Key laws include the General Data Protection Regulation 2016 (GDPR), Data Protection Act 2018 (DPA), Freedom of Information Act 2000 (FOIA), the common law duty of confidence and Human Rights Act 2000 (HRA).

The provider is also responsible for compliance with all NHS policies and procedures and ensuring it complies with the mandatory assertions in the Data Security and Protection Toolkit (DSPT) for the service provision.

The same standards apply to any sub-contractors the provider appoints and in the case of a sub-contractor who is data 'Processors' as defined by the DPA 2018 approval must first be sought from the data 'Controller'.

3.9 Complaints

The provider must comply with the CCG complaints procedure and notify WCCG of any complaints, as appropriate:

Complaints can be made via:

- Telephone 0151 541 5380
- Email complaints.nhswirralccg@nhs.net
- Writing to: Corporate Affairs Team, NHS Wirral Clinical Commissioning Group, 5th Floor, Marris House, Hamilton Street, Birkenhead, Wirral CH41 5AL

3.10 Significant Events

The provider will:

- Supply NHS Wirral CCG with full details of all serious significant events, including details of actions taken to remedy these situations.
- Notify NHS Wirral CCG within 1 working day of any significant event/ incident affecting patients, staff or premises giving rise to concern via the DATIX reporting system available to all practices.

The provider must submit a monthly report of any incidents, including near misses and complaints to

NHS Wirral CCG.

3.11 Termination/ Cancellation Period

Either party can provide 3 months written notice to exit the scheme.

WCCG may terminate the scheme within 28 days if, following the suspension of payments, the contractor fails to re-establish services according to the service specification or take appropriate action to address deficiencies within eligibility criteria.

3.12 Exit Planning

The provider will have a robust exit strategy in place which will come into force should the contract come to an end. The provider will work co-operatively and effectively with NHS Wirral CCG and any other providers and partners to ensure a smooth transition is undertaken.

4. Validation and Monitoring

4.1 Monitoring and PPV

The practice will be subject to routine Post Payment Verification process for validation purposes in respect the delivery of this service.

4.2 Payment

Each practice contracted to provide this service will received £91.25 per annum, per patient. This will be divided into quarterly payments as per the calculation below.

The practice will submit a payment template on a quarterly basis indicating the number of patients for whom this service is provided at the end of that quarter e.g.

$$\frac{24 \text{ (patients)} \times \text{£}91.25 \text{ (price per patient)}}{4} = \text{£}547.50 \text{ per quarter}$$

No more than twice yearly Denosumab injections will be paid. Denosumab injections are an amber drug and therefore funded by NHS Wirral CCG (practice prescribing budgets will not be affected).

5. Applicable Service Standards

5.1 Applicable national standards (e.g. NICE)

The provider will adhere to the following standards (and subsequent updates):

- Care quality Commission Registered (CQC) and be fully compliant.
- All appropriate NICE Guidance
- National Patient Safety Agency
- NHS Commissioning Board Special Health Authority (previously National Patient Safety Agency)

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

- Skills for Health (as appropriate)
- Department of Health, Reference guide for consent for examination or treatment, second edition, July 2009.

5.3 Applicable local standards

The following local policies apply and will be updated and expanded as necessary;

- Mental Capacity Guidance and Deprivation of Liberties Policy
- Patient Identification Policy
- Consent Policy

6. Applicable Quality requirements

6.1 Quality Requirements

The provider will adhere to the NHS Contract Quality Schedule requirements including compliance with;

- Safeguarding Vulnerable People in the NHS- Accountability and Assurance Framework
- Duty of candour
- Never events and serious incident management and investigation
- Infection prevention and control
- Nice standards and guidance

NHS Wirral CCG will undertake periodic quality audits as and when necessary. The provider will work with NHS Wirral CCG to provide all appropriate information to support this work.

6.2 Quality Innovations

Clinical and service innovations will be applied to this service as appropriate. The provider will work towards quality improvement innovations as agreed with NHS Wirral CCG.

6.3 Safeguarding

The provider will assess and make the relevant referral to social services if there are any concerns regarding safeguarding children, vulnerable adults, and other family members. The provider will contribute to the delivery of multi-agency safeguarding plans as appropriate. Staffing structures must be in place to ensure induction of new staff and on-going case and clinical supervision of all staff. This must include safeguarding supervision from an appropriately qualified professional.

6.4 Safeguarding Training

The provider will ensure staff receive safeguarding training in accordance with statutory guidance "Safeguarding Children and Young People: roles and competences for healthcare staff (2014)" & "National Competence Framework for Safeguarding Adults endorsed by Learn to Care- Skills for care- Social Care Institute for Excellence (Galpin & Morrison: Bournemouth University (2010)". The provider must ensure the delivery of a comprehensive annual continuing professional development programme for all staff, ensuring within six months of joining. Staff are to attend multi-agency safeguarding training at the appropriate level, for children and adults.

6.5 Applicable Standards

The provider must comply with the following standards:

Applicable Local Standards:

- Wirral Safeguarding Children's Board Policies and Procedures:
<http://wirralscb.proceduresonline.com/>
- Wirral Safeguarding Adult Partnership Board Policies and Procedures
- Wirral Children's Partnership Council's Guide to Integrated Working (which includes comprehensive guidance on information sharing)
- Wirral MARAC policy and procedure

- Wirral Safeguarding Boards Standards for Safeguarding Children and Adults at risk Annual Audit Section 11 Children Act 2004/Chapter 14 Care Act 2014). Details are available on the WSCB website: <https://www.wirralsafeguarding.co.uk/professionals/section-11-175-audit/>

Applicable National Standards

- Working Together to Safeguard Children (DE/DH 2010/2013/2015)
- Children Act 1989 & 2004
- National Service Framework for Children, Young People and Maternity Services (DH 2004)
- Care Act 2014
- Mental Capacity Act & Deprivation of Liberty Safeguards (2005)
- NICE CG89: When to suspect child maltreatment (2009/2013)

The provider must comply with NHS Wirral CCG's current Safeguarding Assurance Framework as described in the *Commissioned Services Standards for Safeguarding Adults and Children at Risk, 2016*. The Provider will be expected to complete Safeguarding Assurance Framework Dashboards and submit to NHS Wirral CCG annually.

Appendix 1 – Map of Medicine Care Pathway for stable Monoclonal Gammopathy of Undetermined Significance (MGUS)



MoM Care Pathway
for stable MGUS.docx

Appendix 2 – Map of Medicine Care Pathway for stable Chronic Lymphocytic Leukaemia (CLL)



MoM Pathway for
stable CLL.docx

Appendix 3 – Discharge Letter from WHT for patients with Monoclonal Gammopathy of Undetermined Significance (MGUS)



Discharge Letter
from WHT - MGUS.do

Appendix 4 – Discharge Letter from WHT for patients with Chronic Lymphocytic Leukaemia (CLL). This will be delivered following the Map of Medicine Care Pathway



Discharge Letter
from WHT - CLL.docx

Appendix 5 – Use of Denosumab



Use of
Denosumab.docx

Appendix 6 – Read Codes



Read Codes.docx