Provision of Near Patient Testing
Local Enhanced Service Specification

Version Control		
Version	**Date Amended**	**Summary of Amendments**
Near Patient Testing LES Specification November 2019-20	April 2022	Funding updated for 2022-23 Justified
Near Patient Testing LES Specification November 2023-24	May 2023	Funding updated for 2023-24
Near Patient Testing LES Specification November 2023-24	July 2023	Claims information added

In recognition of the changes in the monitoring requirements of the drugs listed in the National Enhanced Service, Cardiff and Vale University Health Board intends to commission these as a Local Enhanced Service (LES) in order to incorporate up to date monitoring.

The drugs and conditions included in this LES are:-

Methotrexate
Ciclosporin
Penicillamine
Leflunomide
Sodium Aurothiomalate
Amiodarone
Lithium
Azathioprine
6-mercaptopurine
Mycophenolate

Introduction

1. All practices are expected to provide essential and those additional services they are contracted to provide to all their patients. This enhanced service specification 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. No part of the specification by commission, omission or implication defines or redefines essential or additional services.

Background

2. The treatment of several diseases 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.

Aims

3. The near patient testing service is designed to be one in which:

(i) therapy should only be started for recognised indications
(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.

Service outline

4. This local enhanced service will fund:

(i) a near patient drug monitoring service in respect of the following specified drugs:

Methotrexate
Ciclosporin
Penicillamine
Leflunomide
Sodium Aurothiomalate
Amiodarone
Lithium
Azathioprine
6-mercaptopurine
Mycophenolate

(ii) a register.

Practices must be able to produce and maintain an up-to-date register of all near patient testing drug monitoring service patients, indicating patient name, date of

birth and the indication and duration of treatment and last hospital appointment

(iii) call and recall.

To ensure that systematic call and recall of patients on this register is taking place either in a hospital or general practice setting

(iv) 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

(v) professional links.

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

(vi) referral policies.

Where appropriate to refer patients promptly to other necessary services and to the relevant support agencies using locally agreed guidelines where these exist

(vii) record keeping.

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

(viii) training.

Each practice must ensure that all staff involved in providing any aspect of care under this scheme have the necessary training and skills to do so

(ix) annual review.

All practices involved in the scheme should perform an annual review which could include:

(a) brief details as to arrangements for each of the aspects highlighted in the LES
(b) details as to any computer-assisted decision-making equipment used and arrangements for internal and external quality assurance
(c) details as to any near-patient testing equipment used and arrangements for internal and external quality assurance

(d) details of training and education relevant to the drug monitoring service
(e) details of the standards used for the control of the relevant condition
(f) assurance that any staff member responsible for prescribing must have developed the necessary skills to prescribe safely.

Untoward events

5. It is a condition of participation in this LES that practitioners will give notification, in addition to their statutory obligations, within 72 hours of the information becoming known to him/her, to the PCO clinical governance lead of all emergency admissions or deaths 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.

Accreditation

6. UHBs are responsible for ensuring that enhanced services are delivered by professionals who are properly qualified to do the job and accreditation of the service should be based upon consideration of the enhanced service specification. This Local Enhanced Service has been classified as requiring **General Accreditation**.

An Enhanced Service that requires General Accreditation is defined as a named GP who has the necessary skills and experience to carry out a contracted specific service or procedure. It provides a means whereby **accredited persons will be responsible and accountable** for the delivery of the enhanced service on behalf of the practice. This enhanced service does not have to be delivered by the accredited GP however where components of the service are delivered by somebody other than the accredited GP, the accredited GP is responsible for ensuring that the appropriate skills are available to deliver the service safely.

General Medical Practice Indemnity

This Enhanced Service is covered by the scheme for General Medical Practice Indemnity (GMPI) which falls under the GMS Contract Wales.

This scheme relates to potential or actual clinical negligence claims arising from incidents on or after 1 April 2019, and captures all General Medical Practice (GP practice) staff undertaking NHS 'primary medical services' as defined in The National Health Service (Clinical Negligence Scheme) (Wales) Regulations 2019

The National Health Service (Clinical Negligence Scheme) (Wales) Regulations 2019, sets out the scope of the scheme, namely "primary medical services" which are defined as health services provided under a contract, arrangement or agreement made under or by virtue of the following sections of the National Health Service Wales Act 2006:

(a) section 41(2) (primary medical services);

(b) section 42(1) (general medical services contracts);
(c) section 50 (arrangements by Local Health Boards for the provision of primary medical services).

The GMPI will include clinical negligence liabilities for NHS work arising from the activities of all GP practice staff, including: GP partners; salaried GPs; locum GPs, if on the All Wales Locum Register; Practice Pharmacists; Practice Nurses; Practice Healthcare assistants; and any other member of staff providing clinical services. GP trainees and trainee nursing students delivering general medical services will also be covered. The GMPI will also cover any healthcare professionals providing the delivery of NHS Primary Care through Primary Care cluster arrangements and any vicarious liability to practices where a cluster-based health professional is providing direct care to the practice's registered patients.
GP Locums who are registered with and working to the terms of the All Wales Locum Register (AWLT) for Wales have access to the scheme for GMPI.

Costs
7. In 2023/24 each practice contracted to provide this service will receive:

Level 1 – laboratory outreach sampling, test and dose
£11.49 per patient, per drug, per year, paid quarterly in arrears

Level 2 – PCO, Health Board or other externally funded phlebotomist or pharmacist etc., practice sample, laboratory test, practice dose and monitor
£114.90 per patient, per drug, per year, paid quarterly in arrears

Level 3 – Practice-funded phlebotomist or pharmacist etc., practice sample, laboratory test, practice dose and monitor
£126.40 per patient, per drug, per year, paid quarterly in arrears

In addition to the above fees, where sampling requires a domiciliary visit to a housebound patient on or behalf of the practice, and not by a member of staff employed by an NHS body to provide community health services, an additional fee would be paid for each separate address visited on that day, £5.48 per visit.

8. Claims

All claims to be submitted via Family Practitioner Payments System (FPPS) in accordance with NWSSP Primary Care Services claim guidance. Enhanced service claims must be submitted within 6 months from the end of the quarter in which the service was provided to ensure payment.

The main general principle of the prescribing and monitoring of a near patient testing drug is that secondary care are responsible for the initiation and

stabilisation of the drug and all the associated monitoring during this time. This includes the prescribing of this drug. Once a patient is stable, and after primary care has been sent and returned the documentation to secondary care agreeing to take over the responsibility, the prescribing and associated appropriate monitoring is the responsibility of primary care.

When a patient is started on a near patient testing drug the secondary care clinician will send a "consultant request shared care / near patient testing" form to the appropriate GP practice. This is an advance request and should be completed and returned to the requesting clinician.

Once the patient is on a stable dose of the near patient testing drug, primary care will be asked to undertake near patient testing. Primary care is then responsible for the prescribing and monitoring of the near patient testing drug as detailed in the near patient testing protocols attached.

The attached protocols provide a summary of the monitoring required once the patient is stable. The full near patient testing shared care protocols are sent by secondary care at the time the patient is initiated on the drug. These need to be referred to and kept in the individual patient record.

If a prescribing doctor feels the correct process has not been followed with respect to near patient testing, a shared care incident form is available on the same web page

This should be completed and forwarded to [redacted]

All the documentation and information can be found at:

https://www.wmic.wales.nhs.uk/shared-care-protocols/

Drug: Methotrexate (subcutaneous and oral route) Protocol number 55

Indication: Rheumatoid arthritis and various other auto-immune conditions (e.g. sarcoidosis and vasculitis; Crohn's disease; psoriasis) usually when corticosteroid therapy alone provides inadequate control

General Guidance

This protocol sets out details for the near patient testing monitoring of patients taking **methotrexate** and should be read in conjunction with the General Guidelines for Shared Care.

Background

Methotrexate is an effective second-line drug used in the treatment of rheumatoid arthritis and various other auto-immune conditions. It has both immunosuppressant and anti-inflammatory effects. Methotrexate can be given subcutaneously in those patients who have malabsorption problems or those who are unable to tolerate therapeutic doses of oral methotrexate because of side effects. The hospital will provide adequate training so that the patient or carer self-administers.

Dosage Regimen

Initially 5mg to 7.5mg orally or subcutaneously once weekly, maintenance dose up to 25mg ONCE a week.

Monitoring – Once stable

FBC, LFTs monthly for the first year and then every 3 months

Creatinine & electrolytes every 3 months

Following changes in dose

Repeat FBC and LFTs 2 weeks after dose change (should a dose increase be required)

Drug: Ciclosporin (Neoral) Protocol Number: 29

Indication:Rheumatoid Arthritis

General Guidance

This protocol sets out the details for the near patient testing monitoring of patients taking **ciclosporin**.

Background

Ciclosporin is used as a second-line agent in rheumatoid arthritis or psoriatic arthritis and takes 1-2 months to work. Ciclosporin should be avoided in renal disease or hypertension. Maintain patient on specific brand-do not switch.

Dosage Regimen

RA starting dose: 2.5mg/kg/day (less in obese patients): in 2 divided doses for 6 weeks. Dose may be increased at 2 – 4 weeks intervals by 25mg until clinically effective or the maximum dose of 4mg/kg/day is reached.

Monitoring – Once Stable

Creatinine and electrolytes every 3 months.

FBC and LFTs every 3 months

BP every 3 months (when having 3 monthly blood tests) and should be maintained ≤ 140/90.

Following changes in dose

Repeat FBC, LFT, creatinine and electrolytes 2 weeks after dose change (should a dose increase be required)

Blood ciclosporin levels are not required routinely but may be useful if non-compliance or toxicity is suspected-take blood 12 hours after a dose (i.e. at trough level).

Drug: Penicillamine **Protocol Number: 17**

Indication: Rheumatoid Arthritis

General Guidance

This protocol sets out details for the near patient testing monitoring of patients taking **Penicillamine** and should be read in conjunction with the General Guidelines for Shared Care.

Background

Penicillamine is an effective second-line drug used in the treatment of rheumatoid arthritis

Dosage Regimen

Typical Dose:250-500mg per day in divided doses, by 125mg increments every 4 weeks to 500mg (250mg bd) daily if tolerated. Patients are treated for up to 6 months before deciding on efficacy.

Monitoring – Once Stable

FBC and urinalysis monthly

Patients should be asked about the presence of any skin rash or oral ulceration at each visit.

Following changes in dose

Repeat FBC and urinalysis 2 weeks after dose change (should a dose increase be required)

Drug: Leflunomide **Protocol Number: 11**

Indication: Rheumatoid Arthritis and Psoriatic Arthritis

General Guidance

This protocol sets out details for the near patient testing monitoring of patients taking **Leflunomide** and should be read in conjunction with the General Guidelines for Shared Care.

Background

Leflunomide is used to treat the symptoms of moderate to severe active rheumatoid arthritis and psoriatic arthritis

Dosage Regimen

10 - 20mg once daily when monotherapy is used. In cases of combination therapy with another potentially hepatotoxic DMARD like methotrexate, 10mg once daily is recommended (therapeutic efficacy may be reduced with reduced dosage).
A loading dose of 100mg daily for 3 days may be used to speed up onset of effect but unacceptable gastrointestinal side effects such as diarrhoea may occur so this is often omitted in routine practice.
A loading dose is not recommended when used as part of combination therapy.

Monitoring – Once Stable

FBC, LFTs, body weight and blood pressure every month for the first 6 months and then every 2 months.

(Patients are generally monitored in secondary care for the first 3 months of treatment and handed over to primary care if stable. This may mean patients

require monitoring monthly by primary care until they have had 6 months of treatment when they require monitoring every 2 months.)

Please see full details of monitoring protocol at:
https://www.wmic.wales.nhs.uk/shared-care-protocols/

Drug:Sodium Aurothiomalate **Protocol Number: 19**

Indication: Rheumatoid Arthritis

General Guidance

This protocol sets out details for the near patient testing monitoring of patients taking **Sodium Aurothiomalate** and should be read in conjunction with the General Guidelines for Shared Care.

Background

Sodium Aurothiomalate is a slow-acting drug effective in controlling disease activity in 60-70% of patients with rheumatoid arthritis. Improvement can be expected after 2-3 months (400-600mg total dose), and in the absence of toxicity gold injections can be continued indefinitely

Dosage Regimen

Typical dose: 10mg intramuscular (IM) test dose (which should be given in the clinic followed by a 30 minute observation to look for signs of allergic reaction*) followed by 50mg IM weekly until there is a significant response (not expected until cumulative dose of 500mg has been given) or a total of 1000mg has been given. In patients who respond, the interval between doses may be increased by stages from 50mg per week to 50mg every 4 weeks. If there is no response after a cumulative dose of 1000mg has been given, consider alternative therapy
*Anaphylactoid or nitritoid reactions are rare but may occur just a few minutes after the injection. Dizziness, nausea, vomiting, sweating and facial flushing charaterise them and necessitate discontinuation of treatment.

Dose record cards are available from the hospital and must be carefully maintained.

Monitoring – Once Stable

FBC and urinalysis prior to each injection

The patient should be asked about the presence of pruritis, rash or mouth ulcers bruising, bleeding or any other new symptom before each injection.

Provided blood results are stable the results of the FBC need not be available before the injection is given but must be available before the next injection i.e. it is permissible to work one FBC in arrears.

Urinalysis should be carried out just before each injection.

Drug: Amiodarone **Protocol Number: 44**

Indication: Severe cardiac rhythm disorders where other treatments either cannot be used or have failed

General Guidance

This protocol sets out details for the near patient testing monitoring of patients taking **Amiodarone** and should be read in conjunction with the General Guidelines for Shared Care.

Background

Amiodarone is commonly used to maintain sinus rhythm in patients with atrial fibrillation or who have converted from, or relapsed in atrial fibrillation following cardioversion.

Dosage Regimen

Maintenance dose is usually 200mg daily; however 100mg daily may be sufficient in elderly patients. The minimum dose to control arrhythmia is used. In rare cases a maintenance dose of above 200mg daily may be required.

All dose adjustments will be done by secondary care unless directions have been specified in the medical letter to the GP.

Monitoring – Once Stable

LFTs and TFTs every 6 months
Electrolytes for those on diuretics every 6 months

Drug: Lithium **Protocol Number: 12**

Indication: Prophylaxis of Mania, Bipolar Disorder, Recurrent Depression

General Guidance

This protocol sets out details for the near patient testing monitoring of patients taking **Lithium** and should be read in conjunction with the General Guidelines for Shared Care.

Background

Lithium is used in the prophylaxis and treatment of mania, the prophylaxis of bipolar disorder and the prophylaxis of recurrent depression

Dosage Regimen

A dosage regimen can be established for Lithium prophylaxis by giving 0.15 – 0.20 mmol/kg/day (i.e. 10 – 14 mmol/day in a 70kg man or about 400-600mg/day of Lithium Carbonate). The dose can then be adjusted to achieve a plasma concentration of 0.4 – 1.0 mmol/1 twelve hours after the preceding dose on days 4 - 7 of treatment. Plasma concentrations should then be measured weekly until dosage has remained constant for four weeks and then every three months thereafter

Monitoring – Once Stable

Creatinine, eGFR, electrolytes and calcium (corrected) every 6 months

Thyroid function tests every 6 months

Lithium levels (taken 12 hours post dose) 3 monthly and one week after any dose or preparation changes.

Drug: 6-Mercaptopurine **Protocol Number: 25**

Indication: Inflammatory Bowel Disease

General Guidance

This protocol sets out details for the near patient testing monitoring of patients taking **6-mercaptopurine** and should be read in conjunction with the General Guidelines for Shared Care.

Background

6-mercaptopurine is used as a second line therapy for patients with steroid-dependent ulcerative colitis or Crohn's disease, or where there are frequent relapses or severe disease *(unlicensed indication).* The drug has immunosuppressive and steroid-sparing properties. It may be used in patients intolerant to azathioprine.

Dosage Regimen

The usual starting dose is 50mg daily. The final dose of 6-mercaptopurine is 1.5mg per kilogram.

Monitoring – Once stable

FBC every 2 months
LFTs at 1 month, 2 months, 4 months and 6 months and then every 6 months.

Following changes in dose

Check FBC two weeks after any dose increase (should a dose increase be required)

Drug: Azathioprine **Protocol Number: 51**

Indication: For various auto-immune conditions usually when corticosteroid therapy alone provides inadequate control.

General Guidance

This protocol sets out details for the near patient testing monitoring of patients taking **azathioprine** and should be read in conjunction with the General Guidelines for Shared Care.(There is a separate shared care protocol for solid organ transplants where monitoring is the responsibility of secondary care)

Background

Azathioprine is used for various auto-immune conditions usually when corticosteroid therapy alone provides inadequate control.

Dosage Regimen

The target azathioprine dose will depend upon the patient's weight and baseline thiopurine methyltransferase (TPMT) level as well as any renal or hepatic impairment. The usual maintenance dose is in the range of 1-3mg/kg/day.

Monitoring – Once stable

FBC every 3 months

LFTs at 1 month, 2 months and then every 3 months thereafter

Following changes in dose

Repeat FBC and LFTs 2 weeks after dose change (should a dose increase be required)

Drug: Mycophenolate **Protocol number 53**

Indication: Various conditions, which characteristically respond to immunosuppressive therapy.

General Guidance

This protocol sets out details for the near patient testing monitoring of patients taking **mycophenolate** and should be read in conjunction with the General Guidelines for Shared Care

Background

Mycophenolate is used as second line disease modifying therapy for treatment of various conditions *(unlicensed conditions)* which characteristically respond to immunosuppressive therapy.

Dosage Regimen

Typical dose: 1– 2g/day -Typical starting dose: 500mg daily for the first week, 500mg twice daily for the second week and increased gradually by 500mg each week until the optimum or maximum tolerated dose is reached. In severe or resistant cases a maximum of 1500mg twice daily may be used.

Monitoring –Once stable

FBC every month for the first year and then every three months thereafter.

Following changes in dose

Repeat FBC 2 weeks after dose change and then monthly (should a dose increase be required)