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Bwrdd Iechyd Prifysgol
Hywel Dda
University Health Board



Specification for a Local Enhanced Service for the Monitoring of Near Patient Testing Drugs

1. Introduction

All practices are expected to provide the essential and additional services they are contracted to provide to all their patients. This specification outlines a more specialised service to be provided. The specification of this service is designed to cover enhanced aspects of clinical care of the patient, that go beyond the scope of essential services. No part of this specification by commission, omission or implication defines or redefines essential or additional services.

2. Background

The treatment of several diseases within the field of medicine, particularly in rheumatology, is increasingly reliant on drugs that, while clinically effective, need regular monitoring of blood, urine etc. 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.

3. Service Aim

The Near Patient Testing (NPT) enhanced 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 initiated 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.

4. Service Outline

This Local Enhanced Service (LES) will fund a **near patient testing and shared care drug monitoring service** in respect of the following specified drugs for the following specified conditions:

- a) Amiodarone in severe cardiac rhythm disorders;
- b) Azathioprine in inflammatory bowel disease;
- c) Azathioprine in rheumatoid arthritis;
- d) Ciclosporin (Neoral) in psoriasis and eczema;
- e) Ciclosporin (Neoral) in rheumatoid arthritis and other inflammatory rheumatological conditions;
- f) Leflunomide in rheumatoid arthritis and other inflammatory rheumatological conditions;
- g) Lithium in treatment of Mania, Bipolar Disorder, recurrent depression, aggressive or self-mutilating behaviour;
- h) Mercaptopurine in inflammatory bowel disease;

- i) Methotrexate in rheumatoid arthritis;
- j) Mycophenolate in connective tissue and interstitial lung diseases;
- k) Oral methotrexate in psoriasis and eczema;
- l) Penicillamine in rheumatoid arthritis;
- m) Riluzole in the amyotrophic lateral sclerosis (ALS) form of Motor Neurone Disease (MND);
- n) Sodium Aurothiomalate in rheumatoid arthritis;
- o) Subcutaneous methotrexate (Metoject®) in rheumatoid arthritis and other rheumatological conditions (adults only);
- p) Sulfasalazine in inflammatory bowel disease;
- q) Sulphasalazine in rheumatoid arthritis;
- r) **Drug A¹ for conditions not included in this enhanced service** – if Drug A is being prescribed for conditions not stated in this LES then providing the practice can demonstrate there is evidence the drug is clinically appropriate for treating the indication and submit a robust Shared Care Protocol² from the initiating Consultant which details the monitoring requirements and responsibilities of each party then payment will be made at the appropriate level of delivery.

It may be clinically appropriate for practices to continue monitoring for a period of 3 months after the date of the last prescription and that this would be claimable.

The shared care protocols for the above named drugs can be found on the dedicated Hywel Dda intranet website, found at this URL: [Shared Care Protocols \(sharepoint.com\)](https://sharepoint.com) Practices should follow the up to date agreed shared care protocol available on the website above.

To ensure all practices are up to the basic level required for a level 1 or level 1a service, the contractor must:

- (i) **Produce and maintain an up-to-date register** of all shared care drug monitoring service patients, indicating patient name, date of birth and the indication and duration of treatment and last hospital appointment.
- (ii) Ensure the **systematic call and recall of patients on this register** is taking place either in a hospital or general practice setting.
- (iii) Ensure that all newly diagnosed/treated patients (and/or their carers when appropriate) **receive appropriate education and advice on management of and prevention of secondary complications of their condition.** This should include written information where appropriate.
- (iv) Ensure that all patients (and/or their carers and support staff where appropriate) are **informed of how to access appropriate and relevant information.**
- (v) **Ensure that the patient has an individual management plan**, which gives the reason for treatment, the planned duration, the monitoring timetable and, if appropriate, the therapeutic range to be obtained.
- (vi) **Work together with other professionals when appropriate.** Any health professionals involved in the care of patients in the programme should be appropriately trained.

¹ For the purposes of this enhanced service, the term “Drug A” applies to all drugs listed in this enhanced service specification. It does not refer to drugs that are not listed.

² A checklist can be found at Annex A for use by the Practice and Consultants to ensure robust monitoring requirements have been provided and patient safety is ensured

- (vii) **Produce 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.
- (viii) **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.
- (ix) **Ensure that all staff involved in providing any aspect of care under this scheme have the necessary skills and training to do so.** The level of training will depend upon the level of service being contracted for.

For level 1-3 all practice staff involved must demonstrate completion of recognised training in the provision of monitoring Near Patient Testing (NPT) drugs.

For level 2- 3 all practice staff involved must demonstrate completion of recognised training in the provision of monitoring NPT drugs, that includes details on dosing.

All staff involved will have to demonstrate that they have kept this training up-to-date and provide details of how they intend to do so in the future.

- (x) **Perform an annual review, which could include:**
 - (a) Brief details of how the above arrangements are being met for each of the aspects highlighted in the enhanced service i.e. the register and call and recall system, details of the patient information used, examples of individual management plan and record keeping, training details etc.
 - (b) Details as to any computer-assisted decision-making equipment used and arrangements for internal and external quality assurance.
 - (c) Details of training and education relevant to the drug monitoring service.
 - (d) Details of the standards used for the control of the relevant condition.
 - (e) Assurance that any staff member responsible for prescribing must have developed the necessary skills to prescribe safely.

An annual clinical audit should be carried out.

5. Interpretation of levels of service

LEVEL	PHLEBOTOMY BY EMPLOYEE OF:	SAMPLE PROVIDED AT:	TESTING (ANALYSIS) UNDERTAKEN AT:	DOSING DECISION*
1	HEALTH BOARD	PRACTICE	HOSPITAL LAB	HOSPITAL
1a	PRACTICE	PRACTICE	HOSPITAL LAB	HOSPITAL
2	HEALTH BOARD (e.g. DISTRICT NURSE)	PRACTICE or HOME	HOSPITAL LAB	PRACTICE
3	PRACTICE	PRACTICE	HOSPITAL LAB	PRACTICE

*In the context of this Enhanced Service, "dosing decision" means reviewing the patient's test results and making a decision on whether to continue as before or seek to change the dose; when the practice does this the GP is not expected to make this decision alone but instead is expected to follow the guidelines in the protocol and in most cases seek advice from the Consultant on how to proceed.

6. Adverse Significant Events

Please ensure that any adverse drug reaction is recorded in the patient's notes and communicated to other clinicians involved in the patients care. You must also complete a yellow card which can be

found at the back of the BNF or computer report on the website www.yellowcard.gov.uk and record in the patients notes that the adverse reaction has been reported.

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 Health Board (HB) Medical Director 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.

7. Accreditation

A practice may be accepted for the provision of this enhanced service if it has a partner or partners, employee or sub-contractor, who has the necessary skills and experience to carry out the contracted procedures.

Doctors will need to satisfy, at appraisal, that they have the necessary medical experience, training and competence to enable them to provide for a safe and effective NPT enhanced service.

Doctors delivering this enhanced service should demonstrate a continuing sustained level of activity, conduct regular audits, be appraised on what they do and take part in necessary supportive educational activities.

Those doctors who have previously provided services similar to this enhanced service and who satisfy at appraisal and revalidation that they have such continuing medical experience, training and competence as is necessary to enable them to contract for the enhanced service shall be deemed professionally qualified to do so.

Accreditation is required at practice level for this enhanced service to provide at the different levels. If the practice wishes to change the level at which they have been historically providing the service, they should refer to below PMCAT link and email the Head of GMS informing them of their wish to change service level and supply the appropriate accreditation evidence:

https://nhs.wales.sharepoint.com/sites/HDD_Primary-care/Shared%20Documents/Forms/AllItems.aspx?id=%2Fsites%2FHDD%5FPrimary%2Dcare%2FShared%20Documents%2FGMS%2FEnhanced%20Services%20Accreditations%2FPMCAT%20%20%2D%20Suggested%20Practitioner%20Accreditation%20Guidance%20for%20Health%20Boards%20%20%2D%20Final%2Epdf&parent=%2Fsites%2FHDD%5FPrimary%2Dcare%2FShared%20Documents%2FGMS%2FEnhanced%20Services%20Accreditations

For ongoing provision, year on year, please register your Practice's intention to provide this LES at the agreed level every year via the Annual Return.

7. Pricing

Table 1 below provides the outline of the service levels and associated payments. You may claim a payment for providing each drug at the appropriate level as follows:

Table 1

Level	Description	Per Month*	Per Annum*
Level 1	Laboratory outreach sampling, test and dosing decision*	████	████
Level 1a	Practice sample, laboratory test, laboratory dosing decision*	████	████
Level 2	LHB, Trust or other externally funded phlebotomist or pharmacist etc., practice sample, laboratory test, practice dosing decision*	████	████
Level 3	Practice-funded phlebotomist or pharmacist etc, practice sample, laboratory test, practice dosing decision*	████	████

*Pricing quoted in the above table refers to price per patient per drug

*In the context of this Enhanced Service, “dosing decision” means reviewing the patient’s test results and making a decision on whether to continue as before or **seek** to change the dose; when the practice does this the GP is not expected to make this decision alone but instead is expected to follow the guidelines in the protocol and in most cases seek advice from the Consultant on how to proceed.

Payments will be made upon monthly submission to Contractor Payments, NWSSP, of the numbers of patients who you are responsible for monitoring, in accordance with the [agreed Shared Care protocols](#), at each accredited level. You may not necessarily have drawn blood or prescribed for each patient each month. If a patient has attended hospital for one blood test you may still claim. An annual adjustment at the end of the financial year, based on patient registers as at 31 March will **not** be made.

In addition to the above fees, where the 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 of [REDACTED] would be paid for each separate address visited on that day.

If a patient is prescribed more than one identified drug within this document then the practice may claim for each drug.

Checklist for Robust Shared Care Monitoring of NPT Drugs

Any Shared Care Monitoring protocol between initiating Consultants and GPs for indications not covered by this NPT LES, should cover the following elements as a **minimum**:

1. Background:	Provided?
Drug is licensed for the indication being treated, or	
Where there is no license, evidence (e.g. Cochrane Review) has been sought to confirm the drug is clinically appropriate for the indication being treated	
Evidence that Shared Care arrangements are suitable for patients newly initiated on Drug A	
Evidence that known contra-indications have been considered	
Evidence that known drug interactions have been considered	
2. Dosage	Provided?
Loading Regimen, if appropriate	
Maintenance dose	
Arrangements for dose adjustments (e.g. whose responsibility)	
Drug interactions advice given where appropriate	
Immunisation advice given where appropriate	
3. Adverse Drug Reactions	Provided
Diagnosis	
Alternative drugs	
When to seek Specialist advice	
4. Baseline Investigations	Provided?
Evidence of baseline investigations undertaken by the specialist centre (including results)	

5. Frequency of Monitoring and 'Safe' parameters for (where appropriate – this list is not intended to be exhaustive)	Provided?
Clinical Adverse Effects	
FBC	
U&E	
LFT	
TFT	
Urinalysis	
ESR	
CRP	
Creatinine	
(Serum) Electrolytes	
Eyes	
Fasting Lipids	
Blood Pressure	
Weight / BMI	
WBC	
Calcium	
eGFR	
Thyroid function	
ECG	
Pulse	
Urine Dipstick	

6. Actions to be taken by GP	Provided?
In case of illness or deterioration	
In case monitoring results fall outside the designated 'safe' parameters	
In case of stopping medication	

7. Contact Details of Specialist Centre and Consultants	Provided?
Name(s) of Consultant(s) if advice needed	
Base of Consultant(s) for written correspondence	
Telephone number(s) for urgent advice	

8. Responsibilities	Provided?
Of Initiating Consultant	
Of Primary Care	
Of Patients / Carers	
Of all Prescribers	
Of Pharmacists	

9. Patient Information	Provided?
Patient leaflet / literature provided	