LOCAL ENHANCED SERVICE SPECIFICATION – FORTH VALLEY 2015 /16

Provision of near patient testing - *Revised March 2015*

Significant changes for 2015:

- ***4.1 no changes to list of included drugs or monitoring requirements***
- ***5.4 Bundle data submission no longer required***
- ***7. SEAs no longer required to be submitted*** ***Interface SEAs can still be submitted with WSW work***
- ***8. Changes to practice remuneration.*** ***Removal of one off fee of £100 (this has been transferred to "Shifting the Balance" ES)***
- **Appendix 5 & 6 - *removed –*** ***No SEAs reflection submission and consequently no timeline for 2015-16***

1. Introduction

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.

2. Background

The treatment of several diseases within the field of medicine 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. Although initiation of these drugs is usually the remit of the specialist, increasingly, the monitoring of these drugs is being managed in primary care. Approximately 6% of hospital admissions are due to adverse drug reactions (ADRs)[1] and 3.7% are drug

[1] Pirmohamed M, James S, Meakin S, Green C, Scott AK, Walley TJ, et al. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. BMJ 2004;329(7456): 15-9.

related and preventable[2]. Cytotoxic drugs, like methotrexate, leflunomide and azathioprine, do not cause emergency hospital admission on the same scale as for example, warfarin, as its indications and therefore its use are more limited. However, their inherent toxicity means that they do regularly cause severe harm, including death (although this is rare), and have been the subject of regular National Patient Safety Agency (NPSA) alerts as a consequence[3]. Practices need to ensure that prescriptions for community cytotoxic drugs are appropriate and carefully monitored to minimise risk. Recent data, drawing on work in progress, indicates that the prescribing and monitoring of community cytotoxics is suboptimal and potentially unsafe. Whilst we have seen great improvements, both nationally and locally in the management of these drugs (for example in the number of patients co-prescribed methotrexate 2.5 mg and 10 mg tablets) We need to be able to show that we continue to prescribe and monitor these medications in a reliably safe way.

This enhanced service provides clear guidance to help practices deliver safe, reliable care and provides a framework for measuring care to drive improvement.

3. Aims

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

- The service to the patient is safe, reliable and convenient.
- Therapy should only be started for recognised indications for specified lengths of time.
- The drugs are appropriately prescribed according to current guidance.
- Patients on these drugs are regularly monitored in accordance with guidance to prevent avoidable harm from these drugs monitored regularly.
- Patients are informed about these drugs, their side effects and the need for and process for being monitored.

4. Service outline

Under the terms of this local enhanced service, GP practices will be contracted to:

4.1 **Provide a near patient testing drug monitoring service** in respect of the following specified drugs and in accordance with any local shared care protocols (See appendix 2)

a) Atypical antipsychotics:
   - Amisulpride
   - Olanzapine
   - Quetiapine

[2] Howard RL, Avery A, Slavenburg S, Royal S, Pipe G, Lucassen P, et al. Which drugs cause preventable admissions to hospital? A systematic review. British Journal of Clinical Pharmacology 2007;63(2):136-47.
[3] NPSA. Actions that can make anticoagulant therapy safer. Birmingham: National Patient Safety Agency, 2007.

- Risperidone/*Paliperidone*
- Aripiprazole

b) Immunosuppressant drugs

- Azathioprine and mercaptopurine
- Leflunomide
- Methotrexate
- Penicillamine
- Sodium aurothiomalate / *Auranofin*
- Cyclophosphamide.
- Hydroxycarbamide
- *Mycophenolate*
- *Ciclosporin*
- Tacrolimus
- Dapsone
- Acitretin

c) Sulfasalazine for 1 year only (No payment for mesalazine, balsalazide, -olsalazine)

d) **other drugs that do not appear on this list may be claimed for as a " forced claim". This will be reviewed on a case by case basis, but should require a minimum of 3 monthly assessments done by the practice to qualify**

4.2 **Develop and maintain a register.** Practices should be able to produce an up-to-date register of all patients being monitored under the near patient testing service.

4.3 **Record individual management plans.** Patients on these drugs should have the following information clearly highlighted in their notes:

- their contact telephone number
- diagnosis
- planned duration of treatment, and
- monitoring timetable – see locally agreed guidance in Appendix 1

4.4 **Prescribe appropriately.** Patients should be prescribed the drugs according to the local FV guidelines (see Appendix 2) unless specifically advised by the responsible specialist to do otherwise.

Specifically for patients on methotrexate

- A patient on methotrexate should only be prescribed one strength of tablet, 2.5 mg

- Methotrexate is prescribed to be taken weekly, unless in exceptional circumstances, e.g. for cancer treatment.
- Each prescription details the number of tablets to be taken and the dosage, i.e. 4 x 2.5mg tablets weekly (10 mg).
- The prescription for methotrexate is only issued after review of the patient's blood test (see 4.5 below).

4.5 **Conduct appropriate review of blood test prior to issuing of prescription for Methotrexate and Azathioprine.** Practices require to have systems to ensure that patients' blood tests are reviewed prior to a prescription of high-risk drugs being issued, (as per NPSA guidance).

4.6 **Provide appropriate vaccination.** It is considered best practice that patients on cytotoxics receive appropriate pneumococcal vaccine and an annual flu vaccination. Practices are expected to offer pneumococcal vaccine once only and influenza vaccine annually to all eligible patients. Item of service fee is available for pneumococcal vaccination of appropriate patients.

4.7 **Follow current guidance.** Patients' drug dosing and advice on the interval for blood testing given to the patient follows current local guidance (Appendix 2). NHS Forth Valley Monitoring protocols of all Local Enhanced Service Near Patient Testing drugs can be found at:
http://www.nhsforthvalley.com/__documents/qi/ce_guideline_prescribing/monitoring-protocol-for-les-npt-drugs.pdf

4.8 **Initiation.** If commenced in primary care, provide therapy and monitoring which follows specialist advice and is in line with shared care protocols (see Appendix 2).

4.9 **Have systems for call and recall.** The monitoring frequency should be determined by following local guidance. Blood tests should be taken as closely as possible to the planned date. To ensure that systematic call and recall of patients on the register is taking place, practices should clearly inform patients of the advised dose of their drugs and date of follow-up blood test. This information should be recorded in the patient's notes. There should be systems for identifying patients who do not attend for drug monitoring.

4.10 **Ensure compliance with monitoring.** GP practices are required to consider how to work with individual patients who have difficulties complying with monitoring requirements.

4.11 **Provide patient education.** Practices should ensure that all newly initiated patients (and/or their carers and support staff when appropriate) receive in written form:
- appropriate information about the drugs they are being prescribed
- information about the relevant drug's side effects, and

- what they should do if side effects occur.

The practice should offer the patient written education about their drug and record that this has taken place in the notes annually.

Patients should be asked about any side effects every time drug monitoring is carried out and record that this has taken place in the notes.

4.12 **Ensure staff are trained.** Each practice must ensure that all staff involved in providing any aspect of care under the LES have the necessary training and skills to do so.

4.13 **Generally work in accordance with good practice.** It is considered good practice to:

- Ensure that at initial diagnosis, and at least annually, an appropriate review of the patient's health is carried out, including checks for potential complications and, as necessary, a review of the patient's own monitoring records.
- Ensure that all clinical information relating to the LES is recorded in the patient's own GP-held lifelong record.
- Refer if monitoring show abnormalities in line with current FV guidance (appendix 2)

5. Data Collection by GP practices-clinical

It is important that practices collect regular data on their prescribing and monitoring of these drugs, both to identify where their care is unreliable and to act as a focus for improvement.

5.1 All practices involved in the LES should provide details **monthly** of the number of patients being prescribed all drugs (see 4.1) covered by the service via Primary Care Contractor Services for practice remuneration.

<u>Annual data collection on all NPT patients</u>

5.2 All practices involved in the LES should be able to provide (if required, for example in a practice verification visit), details of the practice system for recognising normal and abnormal monitoring tests, how patients are informed of the results and how they are advised of follow up.

5.3 *Practices are not required to submit annual data as previously*, however we still recommend that this data is collected, annually, maybe as part of the patients annual review:

- the patient's contact phone number
- diagnosis

- current monitoring timetable (see Appendix 1&2)

5.4 Regular "bundle" data collection - no longer needs to be submitted. However, guidance is still included in this version of the ES specification in case practices want to continue to check bundle measures for internal audit

Practices will randomly sample 10 patients on Methotrexate or Azathioprine to see if they are reliably receiving the following care*:*

1. **Appropriate tests are carried out in correct time scale**
   Measure: Has there been a full blood count in the past 12 weeks (AZA) 8 weeks (MTX) as per local guidance (Appendix 2). *If a specialist has stipulated that different monitoring is appropriate for a specific patient, and this is clearly documented, then these guidelines can be followed. This could apply to specialist's outwith FV.*

2. **Appropriate action is taken and documented for any abnormal results in previous 12 weeks**
   Measure: If any significantly abnormal results occurred in the previous 12 weeks has action been recorded in the consultation record? (ref Appendix 2) *Record as YES if no bloods done; record as YES if blood done, bloods abnormal , but has been acted on appropriately; record as NO if bloods done but no action/ incorrect action taken*

3. **Blood tests are reviewed prior to prescription**
   Measure: Is there a documented review of blood tests prior to issue of the last prescription?

4. **Appropriate immunisation**
   Measure: Has the patient ever had a pneumococcal vaccine? *Read as has the patient ever had, or has formally declined, pneumococcal vaccination?*

5. **Side effects**
   Measure: Is it documented that the patient was asked about any new or recent side effects the last time blood was taken for drug monitoring?

6. **Have all elements been met for each patient** - the 'all or nothing' (composite) measure?

See Appendix 3 – Bundle Pack - for the background to this "bundle" approach to Quality Improvement. Here you will find the relevant data collection tool and spreadsheet for data entry and monitoring. Also available is guidance on how to generate random numbers for your patient sampling and how the "all or nothing" (composite) measurement (number 6 above) is documented.

If practices have insufficient patients on Methotrexate and Azathioprine, consideration should be given to applying bundle methodology to other drugs included in NPT monitoring.

At some point, we hope that bundle data will be submitted centrally on line. If and when this happens we will provide you with adequate warning and appropriate training.

6.1 Board data

% of oral Methotrexate prescriptions for non 2.5mg tabs will be available at Board level.

6.2 Practice reflection

Not required as part of the ES for 2015-16

6.3 Collaborative learning

7. Significant event analysis (SEA)

Practices should consider performing a SEA where interface issues relating to anticoagulation has jeopardised patient safety. These should be submitted as per other interface related SEAs through the Whole System Working system

Practices should consider continuing to undertake SEAs for internal use where patients have been harmed, or potentially harmed as a result of high risk drug use but these no longer need to be submitted. However SEAs where interface issues relating to these medications has jeopardised patient safety should be submitted as per other interface related SEAs through the Whole System Working system.

8. Practice remuneration

Each practice contracted to provide this service will receive:

- DMARDs - £95.90 per patient, per annum

- Atypical antipsychotics - £50.00 per patient, as a one off initiation fee (in recognition of decreased work load as per new guidelines). Practices should only consider claiming this if some or all of the appropriate testing has been performed in Primary care.

- Sulfasalazine, £95.95 fee payable only for first year- in accordance with monitoring guidelines. (*Balsalazide, Mesalazine, Olsalazine do not require ongoing monitoring- no fee)*

Practices can claim for the administration of a pneumococcal vaccine in eligible immunocompromised patients as an Item of Service.

The one off payment of £100 has been dropped in recognition of lack of obligation to perform bundle data collection. This funding has been absorbed into the "shifting the balance of care" ES.

Please note that practices may only claim near patient testing fees for patients who are actively being monitored by the practice. As a rule of thumb, monitoring requirements should be at least every 3months to qualify for ES payments. This could be applied to new drugs that practices are asked to monitor that do not appear on the list at 4.1-. Practices should submit a "forced claim" for such drugs

Please also note that practices may elect to sign up to this NPT LES ,as per this specification, with or without care of patients on Atypical Antipsychotics.

9. References

1. Pirmohamed M, James S, Meakin S, Green C, Scott AK, Walley TJ, et al. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. BMJ 2004;329(7456):15-9.

2. Howard RL, Avery A, Slavenburg S, Royal S, Pipe G, Lucassen P, et al. Which drugs cause preventable admissions to hospital? A systematic review. British Journal of Clinical Pharmacology 2007;63(2):136-47.

3. NPSA. Actions that can make anticoagulant therapy safer. Birmingham: National Patient Safety Agency, 2007.

4. SIGN 131 management of schizophrenia

5 physical health guideline & shared care protocol for People with significant mental health problems (FV ADTC 2013)

10. Appendices

Please note: Appendix 3 documents are provided as hyperlinks (hover your mouse over the appendix title and follow the pop-up instructions to access them). Remaining appendices are provided as hard copies on the following pages. Should you require electronic copies of any documents please contact Senior Quality Improvement Facilitator: leslie.simpson@nhs.net

Clinical Material

Appendix 1 has been removed as it has been superceeded by appendix 2

Appendix 2 Monitoring Protocols for all LES NPT drugs. Up to date versions of these guidelines can be found at
http://www.nhsforthvalley.com/__documents/qi/ce_guideline_prescribing/monitoring-protocol-for-les-npt-drugs.pdf

Data Collection

Appendix 3 Bundle pack

Please note: Revised bundle data collection documents are not listed below. These will be distributed to practices when agreed nationally.

a) What is a care bundle?
b) All or nothing explaination (composite measure)
c) Random number generator spreadsheet and instructions
(save to computer prior to adding data)
d) Bundle data collection spreadsheet
(save to computer prior to adding data)
e) NPT bundle element rationale

Appendix 2 Monitoring Protocols for all LES NPT drugs – *Updated March 2014*

NHS Forth Valley Local enhanced service: Provision of near-patient testing

Drug Monitoring Protocol – March 2014 Version
http://www.nhsforthvalley.com/__documents/gi/ce_guideline_prescribing/monitoring-protocol-for-les-npt-drugs.pdf

Drug	Suggested Monitoring	Additional Information
Musculoskeletal and joint diseases (BNF Chapter 10)		
Azathioprine and mercaptopurine (prodrug)	**Baseline:** • FBC, U&Es, and LFTs. • Test for TPMT genotype (by specialist) **Initiation** • FBC and LFTs weekly for the until dose stable for 4 weeks, and then monthly for 3/12 **Routine:** • 3 monthly tests thereafter (4 weekly if TPMT heterozygote) • 2 and 4 weeks after subsequent dose changes	**NB** The BNF advises weekly monitoring of FBC for the first 4 weeks only, and questions the practical value of weekly monitoring for the first 8 weeks. If any of the following results are received, treatment should be withheld until discussed with specialist • Lymphocytes <0.5.x10^9/l • White cell count <3.5.x10^9/l • Neutrophils <1.5.x10^9/l • >2-fold rise in AST, ALT from baseline AND >100
Leflunomide	**Baseline:** • FBC including differential WBC count and platelets, ALT and AST. **Routine:** • FBC, ALT and BP must be checked monthly or at more frequent intervals during the first 6 months and every 8 weeks thereafter.	If any of the following results are received, treatment should be withheld until discussed with rheumatologist: • Lymphocytes <0.5.x10^9/l • White cell count <3.5.x10^9/l • Neutrophils <1.5.x10^9/l • >2-fold rise in AST, ALT from baseline AND >100
Methotrexate	**Baseline:** • FBC, LFTs, U&Es Chest Xray. **Initiation:** • FBC LFTs and U&Es at 1 week, then 3 weekly until dose stable for > 6weeks **Routine :** • FBC LFTs U&Es 8 weekly. Repeat bloods 3 and 6 weeks after any dose change	SPC suggests that FBC, urinalysis, renal function tests, and LFTS are performed every 2-3 months. This monitoring would also apply to patients receiving Methotrexate for the treatment of psoriasis. If any of the following results are received, treatment should be withheld until discussed with relevant clinician. • Lymphocytes <0.5.x10^9/l • White cell count <3.5.x10^9/l • Neutrophils <1.5.x10^9/l • >2-fold rise in AST, ALT from baseline AND >100

Penicillamine	**Baseline:** • FBC and platelet counts, plus renal function (urinalysis, U&Es, creatinine). **Routine:** • Urinalysis and FBC should be checked fortnightly until on a stable dose.	If any of the following results are received, treatment should be withheld until discussed with specialist : platelets <150x10^9/l • Lymphocytes <0.5.x10^9/l • White cell count <3.5.x10^9/l • Neutrophils <1.5.x10^9/l • >++ proteinuria on more than 1 occasion • >++ haematuria on more than 1 occasion
Sodium Aurothiomalate	**Baseline:** • FBC, urinalysis, U&Es, serum creatinine and LFTs. **Routine:** • Before each injection, FBC and urinalysis should be obtained.	It is permissible to work one FBC in arrears. If any of the following laboratory test results are received, treatment should be withheld until discussed with specialist: • Lymphocytes <0.5.x10^9/l • White cell count <3.5.x10^9/l • Neutrophils <1.5.x10^9/l • platelets <150x10^9/l • >++ proteinuria on more than 1 occasion
Sulfasalazine ONLY *<u>Not</u> Mesalazine , Olsalazine or Balsalazide)*	**Baseline:** • FBC (differential white cell, red cell and platelet counts), LFTs, U&Es **Initiation:** • FBC LFTs should be checked at 2 weeks, 4 weeks, 8 weeks and at 12 weeks, **Routine:** • **up to 1 year** -FBC LFTs (including ALT or AST) should be checked 12 weekly for 1 year*FV recommends U&Es 12 weekly too, although this is contrary to some guidelines. • **Beyond 1 year** -annual LFTS FBC and U&ES, usually done at annual specialist review	If any of the following results are received, treatment should be withheld until discussed with specialist: • Lymphocytes <0.5.x10^9/l • White cell count <3.5.x10^9/l • Neutrophils <1.5.x10^9/l • >2-fold rise in AST, ALT from baseline AND >100 **Forth Valley guidelines are that Sulfasalazine should be monitored for 1 year after initiation, and hence eligible for NPT ES claim for 1 year only.**
Cyclophosphamide	**Baseline:** • Full Blood Count • U&Es, LFTs and urinalysis and repeated 4-6 weekly while on drug	
Tacrolimus	**Baseline:** • Patients receiving tacrolimus should have blood glucose, U&Es, FBC and LFTs carried out 3 monthly. In addition blood pressure should be checked 3 monthly and cholesterol 6 monthly while on drug.	

Ciclosporin	**Baseline:** • Patients on Ciclosporin should have FBC, ESR U&Es and BP checked weekly for 4 weeks and then fortnightly for 8 weeks **Routine:** • FBC, ESR, U&Es and BP checked monthly. • Fasting lipids should be checked annually	BNF advises to prescribe as a branded drug name as there is significant variations in bioavailability between different products. Guidelines suggest that persistently raised BP best responds to Ca Channel blockers and if BP remains difficult to control, stopping ciclosporin should be considered
Mycophenolate or Mofetil	**Baseline:** • Patients on Mycophenolate or Mofetil should have FBC and U&Es carried out weekly for 4 weeks and fortnightly for 8 weeks **Routine:** • FBC and U&Es carried out monthly for the first year. Thereafter monitoring should be a carried out on a 3 monthly basis if patient is stable.	
Mercaptopurine	**Baseline:** • FBC and LFTs weekly for 8 weeks then monthly until stable. **Routine:** • FBC and LFTs ESR CRP 3 monthly	
Hydroxycarbomide	**Baseline:** • FBC, U&Es LFTs uric acid on initiation • FBC uric acid weekly for 6 weeks **Routine:** • FBC 4 and 6 weeks after dose changes • FBC uric acid U&Es LFTs 3 monthly	Discuss with initiating Haematologist if: • Hb decrease by 25g/l or Hb <105 g/l (stop and discuss) • PCV >0.45 (for PRV) (venesection required?) • WCC less than 2.5 (or Neut <1.5)(stop and discuss) or more than 20x109/l (discuss) • Platelets < 100 (stop and discuss) or > 400x109/l (discuss) Ask about oral or skin ulceration/sore throat, abnormal bruising, itching, pregnancy. Raised MCV is normal. should co-prescribe aspirin or Clopidogrel and Allopurinol
Dapsone	**Baseline:** • FBC, Retic count, U&Es, and LFTs. • Test for G6PD (by specialist) **Initiation** • FBC, Retic count and LFTs weekly for 6 weeks, and then fortnightly for 2/12	If any of the following results are received, treatment should be withheld until discussed with relevant clinician: • Lymphocytes <0.5.x10^9/l • White cell count <3.5.x10^9/l • Neutrophils <1.5.x10^9/l • >2-fold rise in AST, ALT from baseline AND >100

	Routine: • 3 monthly tests thereafter • 2 and 4 weeks after subsequent dose changes	
Acitretin	**Baseline:** • FBC, LFTs, U&Es, Fasting Lipids including Triglycerides, (Glucose if diabetes) **Initiation:** • FBC, LFTs, U&Es, Fasting Lipids including Triglycerides, (Glucose if diabetes) monthly for 2 months, then 3 monthly **Routine :** • FBC, LFTs, U&Es, Fasting Lipids including Triglycerides (Glucose if diabetes) 3 monthly	If Acitretin is used in a woman of childbearing potential contraception needs to be discussed and undertaken for 3 years If any of the following results are received, treatment should be withheld until discussed with relevant clinician. • Lymphocyte <0.5x10^9/l • Neutrophils <1.5x10^9/l • >2-fold rise in AST, ALT from baseline AND >100 • Fasting Triglycerides >5mmol/L

Atypical Antipsychotics	See below, amended as per SIGN 131 (ref 4, 5)	
Amisulpiride **Olanzapine** **Quetiapine** **Risperidone** **Aripiprazole** **Incl Paliperidone**	**Baseline:** • BMI. BP smoking status. Bloods (cholesterol (incl HDL for QOF(MH14) & glucose or HBA1c) **Routine** • **After 1/12** check BMI • **After 3/12** check BMI cholesterol and glucose or HBA1c • **Yearly** check BMI cholesterol (incl HDL) and glucose or HBA1c • **Check ECG and prolactin if clinically indicated**	Review if: • Investigate/review/ treat raised Glu or HBA1c as per diabetic investigations • prolactin <600mU/l continue medication and repeat if clinically indicated. If 600-2500mU/l and no symptoms continue drug but monitor annually. If symptoms or >2500 review medication options. If not able to change meds refer endocrine clinic • ECG- sig change in pulse (tachycardia, arrhythmias) • QT interval> 450ms*

***Qt interval advice**	Precalculated QTc interval (already corrected for heart rate) on automated ECG interpretations, should always be less than 450ms. These interpretations are pretty reliable If you are reliant on working out the QT interval yourself- qt interval is start of Q wave to end of t wave qt at a heart rate of 60bpm should be <0.42, then take 0.02 off this for every 10nbp above 60 eg 70bpm, qt<0.40 etc