

LOCAL ENHANCED SERVICE
For the provision of shared care drug monitoring (2)

Service Level Agreement

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INTRODUCTION

All practices are expected to provide essential services and those additional services they are contracted to provide to all their patients. They are also encouraged to provide the Directed, National and Local Enhanced services to the populations they serve. The specification for this service is designed to cover the enhanced aspects of clinical care of the patient, which is beyond the scope of essential services.

SERVICE OUTLINE

This agreement is to cover the period commencing 1st April 2009 to 31st March 2010.

CRITERIA

This Local Enhanced Service Specification details the following criteria. The following pages contain some further guidance from the PCT on expected processes, outcomes and deliverables based on this process. On aspiring to this service practices are required to submit plans under each of these items to the PCT.

- (i) Shared Care Drugs
- (ii) Register
- (iii) Call and Recall
- (iv) Patient Education and Continuing Information
- (v) Individual Management Plan
- (vi) Professional Links and Referral Policies
- (vii) Record Keeping
- (viii) Training
- (ix) Review/Audit
- (x) Untoward Events

Criteria One: Shared Care Drugs

Details

- Shared care drug monitoring service in respect of the following drugs:

- (a) Penicillamine
- (b) Auranofin
- (c) Sulfasalazine
- (d) Methotrexate
- (e) Sodium Aurothiomalate
- (f) Ciclosporin
- (g) Azathioprine
- (h) Leflunomide
- (i) Amiodarone

This could cover other drugs where future shared care is appropriate on agreement with the PCT on a case by case basis.

Criteria Two: Register

Details

- Practices should be able to produce and maintain an up-to-date register of all shared drug monitoring service patients, indicating patient name, date of birth and the indication and duration of treatment and last hospital appointment. The PCT may request a copy of the register.

Criteria Three: Call and Recall

Details

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

Criteria Four: Patient Education and Continuing Information

Details

- To 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
- To ensure that all patients (and/or their carers and support staff when appropriate) are informed of how to access appropriate relevant information

Criteria Five: Individual Management Plan

Details

- To 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

Criteria Six: Professional Links and Referral Policies

Details

- To work together with other professionals when appropriate
- Where appropriate to refer patients promptly to other necessary services and to the relevant support agencies using locally agreed guidelines where these exist

Criteria Seven: Record Keeping

Details

- 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

Criteria Eight: Training

Details

- The 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
- Those doctors who have previously provided services similar to the proposed 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.

Criteria Nine: Review/Audit

Details

- The services delivered by this LES will be subject to clinical audit and monitoring will be carried out as part of the annual review of the contract and as part of review of this LES
- All practices involved in the scheme should perform an annual review which should 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

Criteria Ten: Untoward Events

Details

- It is a condition of participation in this LES that practitioners will give notification to the PCT 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. This must be reported within 72 hours of the information becoming known to the practitioner, preferably using the PCT incident reporting form. This is in addition to the practitioner's statutory obligations

DRUG PROTOCOLS

Further information on monitoring & relevance of tests is available from the PCT Head of Medicines Management, Mark Seaton on 01543 465100.

Drug: Penicillamine

Indication: Rheumatoid arthritis

General guidance

1. This protocol sets out details for the shared care of patients taking PENICILLAMINE should be considered alongside any co-existing Essential Shared care Agreement (ESCA) that might be in place.

Background

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

Dosage Regimes

3. 125mg daily, increasing by 125mg increments every 4 weeks to 500mg daily if tolerated. Some patients respond to a lower dose, occasionally 750mg a day is required. If no response in 1 year discontinue treatment. Not to be taken within 2 hours of food.

Monitoring

FBC, U&E, LFTs prior to treatment.

Urinalysis prior to treatment.

FBC, urinalysis every 2 weeks for 8 weeks, 1 week after any dosage increment, monthly thereafter.

Drug: Auranofin

Indication: Active Progressive Rheumatoid Arthritis

General guidance

1. This protocol sets out details for the shared care of patients taking AURANOFIN should be considered alongside any co-existing Essential Shared care Agreement (ESCA) that might be in place.

Background

2. Auranofin in general is less effective, less toxic and slower to induce a remission than intramuscular gold, and clinical benefit may not become apparent for up to 3-6 months.

Dosage Regimes

3. 6mg daily - either 6mg before breakfast, or 3mg bd before meals.

Monitoring

FBC, U&E, LFTs prior to treatment

Urinalysis prior to treatment

FBC, urinalysis every 2 weeks for 3 months then monthly

Withdraw treatment if platelet count falls below 100,000/mm³ or if signs or symptoms of thrombocytopenia occur.

Drug: Sulfasalazine

Indications: Rheumatoid Arthritis, treatment, and maintenance of remission in mild to moderate & severe ulcerative colitis, treatment of active Crohn's disease

General guidance

1. This protocol sets out details for the shared care of patients taking SULFASALAZINE. should be considered alongside any co-existing Essential Shared care Agreement (ESCA) that might be in place.

Background

2. Sulfasalazine (Salazopyrin) is widely used for the long term treatment of rheumatoid arthritis and the other indications listed above. Sulfasalazine is available as both standard and enteric-coated tablets, the latter of which are considered to give fewer GI side effects.

Dosage Regimes

3. Dosage will depend on the condition being treated, and whether maintenance therapy or treatment of an acute attack is being prescribed. Detailed dosage regimes are available in the latest edition of the BNF. Treatment may be continued indefinitely, the usual reason for stopping being loss of benefit. Sulphasalazine is sometimes co-prescribed with other anti-rheumatic agents, when being used for this indication.

Monitoring

FBC, U&E, LFTs prior to treatment.

FBC, LFTs at 3, 6 & 12 weeks, every 3 months thereafter.

Urgent FBC if patient complains of intercurrent illness during initiation of treatment.

Drug: Methotrexate

Indication: Rheumatoid Arthritis, Psoriasis, Malignant Disease

General guidance

1. This protocol sets out details for the shared care of patients taking METHOTREXATE should be considered alongside any co-existing Essential Shared care Agreement (ESCA) that might be in place.

Background

2. Methotrexate is an effective second-line drug used in the treatment of rheumatoid arthritis and psoriasis. It has both immunosuppressant and anti-inflammatory effects.

Dosage Regimes

3. Initially 5mg to 7.5mg orally once weekly, maintenance dose 7.5 to 12.5mg per week.

Monitoring

FBC, U & E, LFTs	prior to treatment
Urinalysis	prior to treatment
FBC	weekly for 6 weeks initially then monthly, any dosage increase should be followed by a FBC one week later
LFTs	3 monthly
U & E, creatinine	6 monthly

Drug: Sodium Aurothiomalate (Myocrisin)

Indication: Active Progressive Rheumatoid Arthritis, Juvenile Arthritis

General guidance

1. This protocol sets out details for the shared care of patients taking SODIUM AUROTHIOMALATE should be considered alongside any co-existing Essential Shared care Agreement (ESCA) that might be in place.

Background

2. 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 (400-600 mg total dose), and in the absence of toxicity gold injections can be continued indefinitely. Severe reactions (occasionally fatal) in up to 5% of patients.

Counselling

3. Patients should be warned to report immediately sore throat, fever, infection, non-specific illness, unexplained bleeding or bruising, purpura, mouth ulcers, skin rashes, and also any breathlessness or cough

Dosage Regimes

4. 10mg IM test dose then 50mg one week later followed by 50mg weekly to a total dose of 500mg. If there is a clinical response, the frequency of injections can be reduced to every 2 weeks up to a total dose of 1g. In the absence of an improvement continue at 50mg weekly to a total dose of 1g. If after 1g there is clinical improvement, reduce the frequency of injections to every 3-4 weeks. If no response after 1g total dose stop gold. Children may be given 1mg/kg weekly to a maximum of 50mg weekly, the intervals being gradually increased

according to response; an initial test dose is corresponding to one-tenth to one-fifth of the calculated dose.

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

Monitoring

FBC, U+E, LFTs prior to treatment
Urinalysis prior to treatment
FBC, urinalysis prior to each injection
(ESR/CRP is useful to assess response to therapy)

Drug: Ciclosporin

Indication: Rheumatoid Arthritis, psoriasis, severe atopic dermatitis, prophylaxis of transplant rejection.

General guidance

1. This protocol sets out details for the shared care of patients taking Ciclosporin should be considered alongside any co-existing Essential Shared care Agreement (ESCA) that might be in place.
2. Due to inequivalence in terms of bioavailability, ciclosporin should be prescribed as a particular brand.

Background

3. Ciclosporin is a potent immunosuppressant, which is virtually non-myelotoxic, but markedly nephrotoxic. It is subject to many drug-drug interactions (consult BNF)

Dosage Regimes

4. The dosage used is dependent on the indication for use – consult BNF

Monitoring

7. Exact monitoring requirements should be in accordance with the Essential Shared Care Agreement for individual patients and conditions

General Requirements:

FBC monthly

Creatinine - baseline levels should be established prior to commencement of treatment by at least two measurements, and should be monitored at two weekly intervals during the first three months of therapy. Four weekly checks thereafter, but frequency may

need to be increased subject to changes in dosage or concomitant drug therapy.

LFTs- every three months for patients co-prescribed NSAIDs

Serum Lipids - every 6 months

U&Es (hyperkalaemia common)

Blood pressure

Drug: Azathioprine

Indication: Rheumatic disease, transplant rejection, myasthenia gravis, inflammatory bowel disease, severe eczema

General guidance

1. This protocol sets out details for the shared care of patients taking AZATHIOPRINE should be considered alongside any co-existing Essential Shared care Agreement (ESCA) that might be in place.

Background

2. Azathioprine is widely used in a number of auto-immune conditions, usually when corticosteroid therapy alone provides inadequate control. It is assumed that general Practitioners will only be responsible for oral therapy.

Counselling

3. Patients should be warned to report immediately any signs or symptoms of bone marrow suppression e.g. inexplicable bruising or bleeding, infection

Dosage Regimes

4. Initial dosing is in the range of 1-3mg/kg daily, but can be up to 5mg/kg daily for the suppression of transplant rejection. Doses can then be adjusted according to response, but consider withdrawal if no improvement within 3 months

Monitoring

FBC Prior to treatment, at least weekly for first four weeks, then at least every three months

Drug: Leflunomide

Indication: Active rheumatoid arthritis (RA), active psoriatic arthritis(PsA)

General Guidance

1. This protocol sets out the details for monitoring requirements for patients prescribed Leflunomide, and should be considered alongside any co-existing Essential Shared care Agreement (ESCA) that might be in place.

Background

2. Leflunomide is used as a disease-modifying anti-rheumatic drug (DMARD) in the above indications. Clinical improvement usually starts after 4-6 weeks.

Dosage Regimes

3. The maintenance dose of Leflunomide is 10-20mg/day orally for RA and 20mg/day orally for PsA. Lower doses may be advisable in the elderly. A three-day loading dose (100mg/day for three days) is an option, but may increase GI toxicity.

Monitoring

FBC, LFT's and ESR (orCRP)	Every two weeks for two months then four weekly thereafter.
BP	Monthly for six months then 8 weekly

NB ESCA States that specialist responsible for pre-treatment checks, prescribing and all monitoring for the first 6 months of treatment, patients will then transfer to care of GP if stable.

Drug: Amiodarone

Indication: Cardiac Arrhythmia

General Guidance

2. This protocol sets out the details for monitoring requirements for patients prescribed Amiodarone, and should be considered alongside any co-existing Essential Shared care Agreement (ESCA) that might be in place.

Background

3. Amiodarone is use in the treatment of arrhythmias, particularly when other drugs are ineffective or contraindicated. It may be used for paroxysmal supraventricular, nodal and ventricular tachycardias, atrial fibrillation and flutter and ventricular fibrillation.

Dosage Regimes

4. 200mg three times a day for one week, reduced to 200mg twice daily for a further week. Maintenance 200mg daily or minimum required to control arrhythmia.

Monitoring

TFT	Prior to treatment & 6 monthly
LFT	Prior to treatment 6 monthly
Chest X-ray & Lung function	Prior to treatment & if Pulmonary toxicity Suspected.
U&E's	Prior to treatment, and those at risk of Potassium or magnesium depletion Regularly
Ophthalmic Examination	Baseline with slit lamp prior to treatment Then annual exam or more frequent if Problems occur.

ONGOING MEASUREMENT & EVALUATION

The ongoing measurement is outlined in the various criteria in the previous section. **The services provided and scope of this LES will be reviewed with the practice as part of the annual contract monitoring process.**

In addition the practice is required to agree with the PCT this service specification/plan at the start of the year.

FINANCE

This agreement is to cover the 12 months commencing 1st April 2009.

Practices will receive: -

Provision 1 -	Externally funded nurse/phlebotomist takes the blood sample, laboratory test, hospital monitor and dose	£10.68
Provision 2 -	Practice funded nurse/phlebotomist takes the blood sample, laboratory tests, hospital monitoring and dose	£27.72
Provision 3 -	PCT, Trust or other externally funded nurse/phlebotomist etc., practice sample, laboratory test, practice dosing	£106.56
Provision 4 -	Practice-funded nurse/phlebotomist etc., practice sample, laboratory test, practice dosing	£117.24

“Doser” (when used in context of dose/dosing) means any person who is suitably trained and qualified who, upon receipt of relevant information from laboratories, with or without computer assisted decision-making equipment, determines the dosage for patients

**PAYMENT WILL ONLY BE MADE UPON RECEIPT OF PRACTICE
SIGNATURE SHEET**

Practice Stamp

**LOCAL ENHANCED SERVICE
For the provision of shared care drug monitoring (2)**

This document constitutes the agreement between the practice and the PCT in regards to this local enhanced service, as specified.

The practice needs to sign and to agree to the following as set out in this protocol.

Signature on behalf of the Practice:

Signature	Name	Date	Job Title/Position

Signature on behalf of the PCT:

Signature	Name	Date	Job Title
	Darrell Jackson		Primary Care Manager

The agreement is to cover the 12 months commencing 1st April 2009.

**PAYMENT WILL ONLY BE MADE UPON RECEIPT OF PRACTICE
SIGNATURE SHEET**