Provision of Near-patient Testing

A National Enhanced Service under the New contractual arrangements

Proposal to offer services from {surgery name} based on the national specification and benchmarking for the monitoring of drugs which require regular blood monitoring and review

Proposal date:

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 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. The drugs are only prescribed under the direction of hospital consultants and traditionally these patients have been followed up and monitored in hospital outpatients. However it is more convenient to patients and reduces pressure on hospital waiting lists if the service is offered in an organised manner in primary care

Local factors

2a Include any special local factors to support your case eg {surgery name} cover very rural population with a widely dispersed population over **sq km. patients have to travel over **miles to reach their nearest hospital outpatients or laboratory. Within this setting, one of the PCT priorities is equity of provision and we would submit that our patients should not need to travel large distances to hospital care if the service can be provided efficiently and safely within primary care. Patients living close to hospital laboratory have the advantage of easier access to services compared to our very rural population some of whom might need ambulance transport to get to hospital care.

Consultation with patients who need this service has strongly suggested they would prefer to have this service through the surgery rather than hospital attendance which would required in the absence of this enhanced service.

Aims
3. The near patient testing 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.
Service outline

4. This national enhanced service covers:

(i) a shared care drug monitoring service in respect of the following specified drugs:
   (a) Penicillamine
   (b) Auranofin
   (c) Sulphasalazine
   (d) Methotrexate
   (e) Sodium Aurothiomalate.

This could also cover all ‘amber’ lists drugs where shared care is appropriate

(ii) a register. Practices will 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

(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) education and newly diagnosed patients. 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

(v) 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

(vi) individual management plan. 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. Copies of the routine protocols to be followed in the monitoring of 5 named drugs are shown in the Appendix 1

(vii) 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

(viii) 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

(ix) 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

(x) 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

(xi) annual review. This will include the following

(a) brief details as to arrangements for each of the aspects highlighted in the National Enhanced Service
(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 NES 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. The doctors in the practice have previously provided services similar to the proposed enhanced service and will be required to 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.

Costs
7. In 2003/04 each practice will contract to provide this service using the following national tariff: £100 per patient per year.

Volume: {surgery name} would expect to deliver this service for **funded patients in the first year. The contract would be monitored on a quarterly basis and the PCT alerted to significant over-performance. However, during the first year of operation the practice would continue to offer the service if the allocated funding cap was reached and this over-performance would be used to inform contract negotiations for the subsequent year.

Total contract value = £**** per year

(b) This contract would run from 1st April 2004 to 31st March 2005

For further information or queries about this proposal please contact:
APPENDIX 1 – Protocols for use within service provision

### Drug: Sulphasalazine
**Indication:** Rheumatoid Arthritis

**General guidance**
1. This protocol sets out details for the shared care of patients taking SULPHASALAZINE.

**Background**
2. Sulphasalazine (Salazopyrin) is widely used for the long term treatment of rheumatoid arthritis. There are two preparations in use, Salazopyrin EN, (oval, film coated) and generic sulphasalazine (round, uncoated). The former is considered to have less GI side effects.

**Dosage Regimes**
3. 500mg daily increasing by 500mg weekly increments to a maximum of 1g bd, if tolerated. Some patients may respond to a lower dose. Treatment may be continued indefinitely, the usual reason for stopping being loss of benefit. Sulphasalazine is sometimes co-prescribed with other anti-rheumatic agents.

**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: Sodium Aurothiomalate (Myocrisin)
**Indication:** Rheumatoid Arthritis

**General guidance**
1. This protocol sets out details for the shared care of patients taking SODIUM AUROTHIOMALATE.

**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.

**Dosage Regimes**
3. 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. If there is clinical improvement, reduce the frequency of injections to every 3-4 weeks. If no response after 1g total dose stop gold.
4. 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: Auranofin
**Indication:** Rheumatoid Arthritis

**General guidance**
1. This protocol sets out details for the shared care of patients taking AURANOFIN.

**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

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**Drug: Methotrexate**
**Indication: Rheumatoid Arthritis, Psoriasis**

**General guidance**
1. This protocol sets out details for the shared care of patients taking METHOTREXATE.

**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 week initially then monthly, any dosage increase should be followed by an FBC one week later
- LFTs 3 monthly
- U & E, creatinine 6 monthly

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**Penicillamine**
**Indication: Rheumatoid arthritis**

**General guidance**
1. This protocol sets out details for the shared care of patients taking PENICILLAMINE.

**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.