All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

PROPOSAL TO UPDATE NEAR PATIENT TESTING ENHANCED SERVICE

1.0 ACTION BY AWMSG:

The All Wales Medicines Strategy Group (AWMSG) meeting held on 15th December 2010 considered and approved the recommendations outlined below, relating to medications that, in addition to existing medications, should have clearly defined local commissioning arrangements within NHS Wales.

2.0 PURPOSE:

Since 2003 a number of medications have been identified that would be appropriate for a shared care arrangement. A National Enhanced Service (NES) currently provides resource for a small range of such medications to be managed in primary care, however there is currently no national mechanism to update this list. Regions have developed Local Enhanced Services to cover some additional medications but there is significant interregional variation. In order to support appropriate primary care management, there is a need for all Wales guidance to support local commissioning arrangements.

3.0 SUMMARY:

All Wales Prescribing Advisory Group (AWPAG) recommends further treatments to those already included under the GMS near patient testing NES that would be appropriate for delivery in this way. Four recommendations for consideration are highlighted below relating to shared care arrangements. Existing medications are outlined in Table 1, and the medications that should have clearly defined local commissioning arrangements are outlined in Table 2.

This paper was developed in discussion with the Senior Medical Officer for General Practice and Primary Care and the Assistant Medical Director Group.

4.0 BACKGROUND:

Within the context of the increasing delivery of healthcare in the community setting, AWPAG and the Welsh Interface Pharmacists have considered medications which are suitable for shared care but which require significant blood and/or clinical monitoring to avoid potentially serious adverse effects.

The NES for provision of Near Patient Testing drug basket outlined in the General Medical Services (GMS) contract 2003 currently applies to the monitoring of penicillamine, auranofin, sulphasalazine, methotrexate and sodium aurothiomalate (see Appendix1).

The NES service specification states that, "This could also cover all 'amber' lists drugs where shared care is appropriate"[1,2]. However without active development of the NES, local arrangements have developed, without consistent guidance for monitoring or an agreed remuneration.

A model Local Enhanced Service could be developed to ensure consistency. This approach would reduce regional variations in enhanced service provision, particularly Near Patient Testing (NPT). Local implementation will depend upon local service structures and resource.

5.0 RECOMMENDATIONS:

1. Medicines currently included under GMS Near Patient Testing National Enhanced Service (NES) should remain[1]:
Penicillamine, auranofin, sulphasalazine, methotrexate and sodium aurothiomalate.

2. AWMSG strongly recommends that the following therapies, which have been assessed as suitable for shared care following national multiprofessional consultations, are monitored according to national guidance with clearly defined local commissioning arrangements. These are:
Leflunomide, azathioprine, subcutaneous methotrexate, and amiodarone

It is essential that an alternative prescribing option is available to accompany a shared care protocol given their non-obligatory nature. Inclusion in an enhanced service is likely to increase uptake of community monitoring.

An extract of general guidance for enhanced service shared care prescribing (outlined by Caerphilly Health Board previously) is provided below:

Shared care guidelines are intended to provide clear guidance to General Practitioners (GPs) and hospital prescribers regarding the procedures to be adopted when clinical (and therefore prescribing and financial) responsibility for a patient's treatment with a shared-care drug is transferred from secondary to primary care. If the GP is not confident and competent to undertake this role, then they are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks a GP to prescribe this drug, the GP should reply to this request as soon as practicable. The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequence of its use.

3. AWMSG recommends that lithium should be prescribed under shared care arrangements to ensure that roles and responsibilities are clearly defined and agreed.

4. AWMSG recommends that a process is agreed whereby medications, such as those endorsed by AWMSG as suitable for shared care, may be considered for inclusion within an enhanced service.

Medications included in the Model Local Enhanced Service will be reviewed at least annually by AWPAG with subsequent recommendations to AWMSG. The recommendations endorsed will be considered by the Assistant Medical Directors Group for inclusion in Local Enhanced Service arrangements.

Table 1 summarises the monitoring requirements, potential toxicity and volumes of use of the medications under discussion. Table 2 also indicates the level of monitoring for

individual medicines. Frequency will be subject to local arrangements are not therefore considered definitive.

TABLE 1: MEDICINES CURRENTLY INCLUDED UNDER GMS NEAR PATIENT TESTING NATIONAL ENHANCED SERVICE (NES)

GROUP 1	Indication	BAD/BSR monitoring advice (2008)[3]	Volume of use in primary care. Items April 09 – March '10
Existing		**In addition to usual responsibilities of a GP participating in shared care**	
Penicillamine	Rheumatology	BSR: FBC and urinalysis every two weeks until dose stable for three months and then monthly. Patient should be asked about the presence of rash or oral ulceration at each visit.	1,344
Auranofin	Rheumatology	BSR:FBC and urinalysis every four weeks Patient should be asked about the presence of any skin rash or oral ulceration at each visit.	52
Sulphasalazine	Rheumatology	BSR and BAD: FBC and LFTs monthly for the first three months and three monthly thereafter. If, following the first year, dose and blood results have been stable, frequency of blood tests can be reduced to every six months for the second year of treatment; thereafter, monitoring of blood for toxicity may be discarded.* Repeat FBC, LFT one month after dose increases. Patient should be asked about the presence of any skin rash or oral ulceration at each visit. *not universally adopted	52 942
Methotrexate, oral	Rheumatology	BSR: FBC, U&E, LFT every two weeks until dose of methotrexate and monitoring stable for six weeks; thereafter monthly until the dose and disease is stable for 1 yr. Thereafter the monitoring may be reduced in frequency based on clinical judgement	(tablets, liquid & injections) 106 732
	Other e.g. dermatology	BAD: Initially once a week FBC,U&E, creatinine, LFTs; gradually increase interval between tests until therapy stabilized; thereafter monitor every two to three months.	
Sodium aurothiomalate		BSR: FBC and urinalysis at the time of each injection. The patient should be asked about presence of rash or mouth ulcers before each injection.	850

Key: BAD= British Association Dermatologists; BSR= British Society for Rheumatology; FBC=Full Blood Count; LFT=Liver Function test; U&E= Urinalysis and electrolytes

TABLE 2: ADDITIONAL MEDICINES CONSIDERED APPROPRIATE FOR MONITORING UNDER THE NES, NEAR PATIENT TESTING

GROUP 2	Indication	BAD/BSR monitoring advice[3] In addition to usual responsibilities of a GP participating in shared care	Potential toxicity/administration issues	Volume of use in primary care. Items April 09 – March '10
Leflunomide[2] AWMSG endorsed as suitable for shared care	Rheumatology	BSR:FBC, LFTs Every two to four weeks for the first six months (NB: SPC states every two weeks)[4]; if stable, two monthly thereafter	Long half life. Washout procedure important hypertension, myelosuppression, hepatotoxicity, overwhelming sepsis, dizziness, paraesthesia	10,588
Azathioprine[2]	Rheumatology	BSR: FBC and LFT's weekly for six weeks and continue every two weeks until dose stable for six weeks; then monthly. FBC, LFT weekly until stable on maintenance dose. If maintenance dose is achieved and stable for six months consider discussing with patient to reduce monitoring to three monthly. In patients heterozygote for TPMT, monitoring should continue at monthly intervals at minimum. (SPC states weekly for eight weeks, more frequent if high dose or severe hepatic / renal impairment)[5]	Cytotoxic Myelosuppression, Overwhelming sepsis SPC states that patients receiving immunosuppressive therapy are at an increased risk of developing non-Hodgkin's lymphoma and other malignancies, notably skin cancers[5]	47,935 Mercapto-purine 1,480
	Other indications e.g. Inflammatory bowel disease, or Dermatology.	BAD: FBC and LFTs weekly until stable on maintenance dose. If maintenance dose is achieved and stable for six months consider discussing with patient to reduce monitoring to three monthly. In people heterozygote for TPMT, monitoring should continue at monthly intervals at minimum		

GROUP 2 Continued…	Indication	BAD/BSR monitoring advice[3]	Potential toxicity/ administration issues	Volume of use in primary care. Items April 09 – March '10
		In addition to usual responsibilities of a GP participating in shared care		
Subcutaneous methotrexate[2] **AWMSG endorsed as suitable for shared care**	Rheumatology	BSR: FBC, U&E, LFT every two weeks until dose of methotrexate and monitoring stable for six weeks; thereafter monthly until the dose and disease is stable for 1 yr. Subsequent monitoring may be reduced in frequency, based on clinical judgement with due consideration for risk factors	Cytotoxic myelosuppression, hepatotoxicity, pneumonitis	Included in figure above.
	Other indications	BAD: Initially once a week FBC, U&E, creatinine, LFTs; gradually increase interval between tests until therapy stabilized; thereafter monitor every two to three months.		
Amiodarone[2,6] **AWMSG endorsed as suitable for shared care**	Cardiology / general medicine/ geriatrics	Minimum of blood and clinical monitoring every six months	Significant potential toxicity (see section 6.1)	47 069

Key: BAD= British Association Dermatologists; BSR= British Society for Rheumatology; FBC=Full Blood Count; LFT=Liver Function test; U&E= Urinalysis and electrolytes; SPC=Summary Product Characteristics

6.0 FURTHER INFORMATION:

6.1 AMIODARONE

Local audits have shown that blood monitoring of amiodarone is variable. The need for clinical monitoring is often unrecognised[6].

The cost of funding the enhanced service can be considered in light of the risk of the potential major toxicity of amiodarone and associated morbidity and mortality. For example, the summary of product characteristics (SPC) for amiodarone highlights pulmonary toxicity (a common adverse event i.e. [≥1% and <10%]) can sometimes be fatal, and also endocrine disorders such as hypothyroidism or hyperthyroidism[7].

Cases of amiodarone–related pulmonary toxicity in North Wales have driven a review of patients[8]. "Guidance for patients started historically on amiodarone" has undergone national consultation and has been endorsed by AWMSG in August 2010. This includes an audit sheet for practices to review each patient prescribed amiodarone.

All patients included in an amiodarone enhanced service should have an appropriately actioned audit form in their record which demonstrates that continued therapy is consistent with national guidance.

6.2 LITHIUM

With regards to lithium therapy, currently GPs are remunerated under the Quality and Outcomes Framework (QOF) Mental Health indicators to ensure that it is monitored[9,10]. However the National Institute for Clinical Excellence (NICE)[11] and National Patient Safety Agency (NPSA)[12] currently recommend more frequent monitoring than QOF (see Table 3 below).

TABLE3: COMPARISON OF MONITORING RECOMMENDATIONS

Monitoring	QoF (updated August 2010)[9,10]	NICE[11]/ NPSA[12]
% patients of patients on lithium therapy with a record of serum creatinine and thyroid stimulating hormone	within the preceding nine months[9]	six months
% patients of patients on lithium therapy with a record of lithium levels in the therapeutic range	within the previous four months[10]	three months

The responsibility for lithium blood testing and response to abnormal results currently varies within and between localities. This has significant implications for patient safety.
A locally agreed shared care protocol would clarify local roles and responsibilities.
GP remuneration should depend on the level of service provided in primary care.

The NPSA patient safety alert published in December 2009 highlights action for all organisations in the NHS and independent sector where lithium therapy is initiated, prescribed, dispensed and monitored. An executive director, nominated by the chief executive, working with relevant medical, nursing and pharmacy staff and the lead biochemist providing services to the trust, should ensure that by 31 December 2010:

1. Patients prescribed lithium are monitored in accordance with NICE guidance;
2. there are reliable systems to ensure blood test results are communicated between laboratories and prescribers;
3. at the start of lithium therapy and throughout their treatment patients receive appropriate ongoing verbal and written information and a record book to track lithium blood levels and relevant clinical tests*;
4. prescribers and pharmacists check that blood tests are monitored regularly and that it is safe to issue a repeat prescription and/or dispense the prescribed lithium;
5. systems are in place to identify and deal with medicines that might adversely interact with lithium therapy.

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Appendix 1: National Enhanced Service - provision of near-patient testing[1]

2 May 2003 (Updated December 2003)

National Enhanced Service - provision of near-patient testing

2 May 2003 (Updated December 2003)

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.

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 will fund:
(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

Practice requirements outlined in Appendix

(ii) a register. Practices should be able to 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
(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. 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 NES
(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
(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. 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.