Pharmacy Directorate - Policy P/SC/2.1

SHARED CARE ARRANGEMENTS FOR AMBER MEDICINES
FACILITATING TRANSFER OF PRESCRIBING FROM SECONDARY CARE TO PRIMARY CARE

AIM
The aim of this policy is to ensure a consistent and effective approach to the development of shared care arrangements, which will facilitate the safe and effective transfer of prescribing from secondary to primary care.

INTRODUCTION
The 'Traffic Light' system, developed by Northamptonshire Prescribing Advisory Group (NPAG) in 2004 and agreed by KGHFT, NGHFT,NHFT and Nene and Corby CCGs, is designed to facilitate the safe and effective transfer of prescribing from secondary to primary care. The list of medicines and their traffic light classification, and the explanatory document can be viewed at the Pathfinder website: http://nww.pathfinder-rf.northants.nhs.uk/nene/therapeutics/traffic-light-drugs

Medicines are classified as "Amber" if it has been decided they should only be prescribed under "shared care arrangements". Such medicines should usually only be prescribed if they have been recommended after specialist referral. The amber category can be split into two sections, defined as follows:

AMBER 1: These are medicines that require significant monitoring and the decision to treat with an AMBER medicine should be made by specialists only. Prescribing may be transferred to a GP under a shared care protocol. Therapy should either be initiated and the patient stabilised by the specialist, or the specialist may recommend the initial dose for the GP to prescribe while continuing to monitor the patient closely during the stabilisation phase; this will be specified in the shared care protocol e.g. for leflunomide and all other DMARDs. Amber 1 medicines attract a "near patient testing fee" under the GP Local Enhanced-Service Contract

AMBER 2: These are medicines that require little or no monitoring by the GP, but should be prescribed in general practice only after they have been recommended following specialist referral**.** Shared care guidance will be available but a full shared care protocol is not required as little or no monitoring is required. However, GPs must still be provided with the required information by the hospital consultant; the duration of treatment must be specified and the possible consequences of treatment that would necessitate stopping treatment must be identified. Amber 2 medicines do NOT attract a "near patient testing fee" under the GP Local Enhanced-Service Contract.

PRINCIPLES

- As the person who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use, prescribers in primary care must be invited by the specialist to participate in a shared care arrangement. Wherever possible this should be via the pre-formatted 'letter to request shared care' which is part of all agreed shared care protocols (see appendix 1). If the prescriber in primary care is not clinically confident to participate in the shared care arrangement, then he or she is under no obligation to do so. In such an event, total clinical responsibility for the patient for the diagnosed condition remains with the specialist. The NPSA Alert on Methotrexate requires that the GP's consent to the shared care arrangement is documented.

Prepared by: Project Development Pharmacist
ce\c:\documents and settings\pclarke\local settings\temporary internet files\content.outlook\l9z6my8x\sc02v2-1-pdh.doc
Date: July 2007
Last Review: September 2014 Next Review: September 2016

- The incidence of GPs declining a request to a shared care arrangement is expected to be rare, provided that full support is offered by the consultant under that shared care arrangement. The Shared Care Request Letter provides for the proposed arrangement to be declined; this provision may be used in exceptional cases, with a good reason clearly stated. Issues surrounding refusals will be reviewed if necessary and the frequency and consequences of refusals may be assessed through audit.

- Prescribing of all amber 1 medicines under a shared care arrangement must be supported by a written shared care protocol (see Appendix 2). Where a protocol is not available or needs reviewing, at least one clinician and a Nurse Specialist (if in post) must be nominated by the specialty, and the CCGs should ideally nominate at least one GP, to work with Pharmacy to develop a suitable protocol to be reviewed by the Trust's medicine management committee (at KGHFT, NGHT or NHFT) and the Northamptonshire Prescribing Management Group, and recommended for formal approval by NPAG. Where no GP representative is nominated, the draft protocol prepared in Secondary Care will be reviewed by the Northamptonshire Prescribing Management Group

- When a new shared care protocol is developed for an amber 1 medicine, all specialties that prescribe that medicine will be consulted to establish consistency in monitoring requirements wherever this is feasible.

- The shared care protocol must be sent to the GP with the shared care request letter, or directed to the Pathfinder website

- If no shared care protocol is available for a particular amber 1 medicine and cannot be prepared sufficiently quickly, interim monitoring guidelines must be provided by the specialist and accompany the shared care request letter. The interim monitoring guidelines should be standardised to the medication wherever feasible.

- It is the responsibility of the clinician arranging monitoring to ensure that copies of laboratory results are sent to the 'partner' clinician.

- Shared care protocols already in operation are available on the Pathfinder website; new shared care protocols or interim monitoring guidelines will be posted on this site as they are developed to support GPs already participating in less formal shared care arrangements.

- Arrangements will be made with the commissioning body for the GP Local Enhanced-Service Contract to audit shared care arrangements as appropriate.

- The CCGs will be responsible for investigating GP-incidents arising under this scheme, and the Trust will investigate hospital-incidents.

- Patient Consent
  - The NPSA Alert on Methotrexate requires that the patient's consent to the shared care arrangement is confirmed, as well as the patient's understanding of treatment.

  - If the medicine is to be used outside its licensed indication or dose range, GMC Guidance on Good Prescribing Practice should be followed; if appropriate, the patients' consent should be documented and the patient advised that the (manufacturer's) PIL does not cover the condition being treated.

    It is recommended that the GMC Guidance on Good Prescribing Practice should be followed – this includes advice on obtaining patient consent. NPAG currently agrees the best way to meet this requirement is for the consultant (and GP as appropriate) to document what information has been given to the patient and confirm that the patient is in agreement with the shared care arrangement. The issues surrounding patient consent are to be reviewed regularly.

Appendix 1

Northamptonshire Prescribing Advisory Group

NHS

……Clinic ……..**(Consultant)**

Letter to request Shared Care of an Amber Medicine …… **(Date)**

Dear Dr.

Re: Surname Hosp. No.

First name(s): D.O.B.

Your patient attended …… Clinic on……

Diagnosis:

Treatment history:

or see attached letter

Request to Share Care:…….. has been categorised by NPAG as an AMBER 1 drug and, as such, is covered by the near-patient testing enhanced service. I am requesting your consent to the shared care of your patient and the transfer of prescribing only / and monitoring (delete as applicable) as detailed in the agreed Shared Care Protocol. If you are in agreement please prescribe treatment as below.

Medicine name (IN FULL AND BLOCK CAPITALS)……

which is licensed / unlicensed (delete as applicable) for…… (insert indication being treated).

Your patient has been stabilised on the above medicine. Please prescribe the following treatment:

Medicine name (brand if applicable): ……Presentation: ……Strength: ……

Dosage regime (including day of week and no. of tablets, if appropriate):……

Prescribe treatment from ……(insert date of transfer of care) until……

I will reassess your patient in …… weeks from the date of transfer of care to you and ……monthly thereafter. I will send you a written summary within 14 days of each visit.

The following preliminary tests have been carried out in secondary care (test results are attached / will be sent to you direct electronically by the Pathology Lab):

This section MUST be completed.

I will / Please could you (delete as applicable) arrange and monitor the following tests (please specify test schedule):

(Amber 1:If no SCP is available please state why the tests are required and attach interim monitoring guidelines):

The medical staff will be available to give advice and support; please refer to the attached SCP or interim monitoring guidelines for full details. In addition to routine follow-up, I will accept referral for reassessment at your request if you have any concerns about this patient at any time. In the event of an emergency, care of your patient will revert to ……Trust…….…… Department.

Signature (and designation): Date:

Appendix 1

Northamptonshire Prescribing Advisory Group

PATIENT INFORMATION

I confirm I have explained to the patient: the risks and benefits of treatment, the baseline tests conducted, the need for monitoring, how monitoring will be arranged, and the roles of consultant, GP and patient in shared care. I confirm the patient has understood and is satisfied with this shared care arrangement at this time. The patient has been given the following written information.

Signature (and designation):.....

The patient has been given the following information by me as the GP:

Signature of GP:.....

Please return this form as soon as possible. If you have any concerns about the recommended treatment or monitoring arrangements, please contact me immediately, before returning this form.

GP RESPONSE

- I am willing to accept this shared care arrangement for this patient as laid out in the Shared Care Protocol or on the attached monitoring guidelines. ☐
- I am willing to prescribe the medicine as recommended, but would like monitoring to remain the responsibility of the hospital consultant. (In this case, the hospital consultant will need to arrange for the GP to be advised in a timely manner of both the results of monitoring blood/biochemical test results and prescribing instructions.) ☐
- Having discussed my concerns with the hospital consultant, I am NOT willing to accept the shared care arrangement for this patient. ☐

State reason why shared care arrangement has been declined:

Signature of GP: Date:

In the exceptional event that this request to share care is declined, please send a copy of your reply to:
Prescribing Team, NHS Nene and NHS Corby Clinical Commissioning Groups, Francis Crick House, Summerhouse Road, Moulton Park Industrial Park, Northampton NN3 6BF.
AND either:

For patients under the care of the Acute Trust: Duane McLean, Chief Pharmacist, KGHFT NHS Foundation Trust, Rothwell Road, Kettering NN16 8UZ **OR** Paul Rowbotham, Chief Pharmacist, NGHT NHS Trust, Cliftonville, Northampton NN1 5BD.	For patients under the care of NHFT: Michaela Cox, Chief Pharmacist NHFT Berrywood Hospital, Duston, Northampton. NN5 6UD **OR** Russell Parsons, Senior CHS Pharmacist, NHFT Berrywood Hospital, Duston, Northampton NN5 6UD

Prepared by: Project Development Pharmacist
ce\c:\documents and settings\pclarke\local settings\temporary internet files\content.outlook\l9z6my8x\sc02v2-1-pdh.doc
Date: July 2007
Last Review: September 2014 Next Review: September 2016

SHARED CARE PROTOCOLS FOR AMBER 1 MEDICINES

DEVELOPMENT

When protocols are developed (by a team comprising representatives from Secondary and Primary Care and KGHFT / NGHT / NHFT Pharmacy Department, as appropriate) the information will be provided on 2 sides of A4 paper; this necessarily means that clinical information about the disease state, diagnostic criteria and management options will not be included. The 2 sheets (Roles & Responsibilities; and Monitoring & Advice) will be published as two separate documents next to the drug entry on Pathfinder.

GENERAL OBJECTIVES

- To provide a comprehensive summary of treatment.
- To define the areas of responsibility for the sharing of care of the consultant and GP, namely monitoring, prescribing and managing ongoing drug therapy
- To define the role of the patient within the shared care arrangement.
- To define the back up care and facilities available to the GP from the hospital.
- To establish effective communication links between all health professionals involved in the care of the patient.

CONTENT

➢ **Shared Care Arrangements (example template, Appendix 3)**

Clear, unambiguous statements specifying responsibility for aspects of care and defined plans should clinical changes be required, will be included under the appropriate headings.

- Hospital Specialist Responsibilities
- General Practitioner Responsibilities
- Patient's role
- Care Pathway (sheet attached as appendix to protocol) if appropriate

Aspects of care to be considered include:

- Responsibility for initiating and stabilising treatment.
- Responsibility for patient education and ensuring compliance.
- Responsibility for assessing whether shared care is appropriate for a patient.
- Process of making shared care arrangements and ensuring prompt and effective communication between partners in shared care.
- Responsibility for prescribing.
- Responsibility for monitoring, interpreting and acting upon tests/investigations.
- Responsibility for monitoring disease state.
- Responsibility for dosing and continued appropriateness of therapy.
- Responsibility for reporting adverse events.
- Responsibility for providing support to GPs.

…and where appropriate

- Responsibility of community/hospital pharmacy/other agency (eg homecare supplier) for supplying medicine.
- Responsibility of practice/CCG/Hospital Trust for financing therapy.

➢ **Communication**

Back up advice and support provided by named individuals with contact details. Action to be taken in case of emergency.

➢ **Monitoring and Advice Sheet**

A summary of the following drug related information especially pertinent to patient care will provided (SPC and BNF should be consulted for full details);

- Licensed indication and source of medication and pharmaceutical information (presentation etc)
- Dosage and administration
- Cautions
- Contraindications
- Side effects
- Therapeutic use
- Drug interactions
- Monitoring guidelines
- Cost

➢ **References**

Literature and sources used in preparation of information, including a link to the electronic SCP document providing hypertext links to external sources to further support GPs participating in shared care.

➢ **Appendix (if appropriate)**

Care pathway agreed by primary and secondary care stakeholders.

Appendix 3

[Specialty] Shared Care Protocol for [AMBER1MEDICINENAME] – Roles / Responsibilities

Sharing of care assumes communication between the specialist, GP and patient, and other members of the care team including specialist nurses and pharmacists. The intention to share care will be explained to the patient by the specialist initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

If a GP is invited by the specialist to participate in a shared care arrangement, the GP should reply to this request as soon as possible. If the GP is not confident to undertake these roles, then he or she is 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.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

Specialist responsibilities

1. Confirm diagnosis. Perform baseline tests.
2. Discuss the benefits and side effects of treatment with the patient. Ensure that the patient understands the dosing regime, and which warning symptoms to report. Refer patient to Nurse Specialist if appropriate.
3. Initiate and stabilise treatment. (In exceptional cases, it may be the practice of the specialty to initiate the treatment and engage the GP in the stabilisation process. This should be made clear in the SCP).
4. Advise the GP by standard letter of the diagnosis and treatment and ask the GP if he/she is willing to participate in shared care, having first obtained the patient's agreement. Advise GP of monitoring tests needed, test intervals and length of period of supply, and date of review appointment. Arrange and monitor blood test results and response to [AMBER1MEDICINENAME] if monitoring undertaken by specialist. Recommend any concomitant therapy.
5. Ensure compliance with any national advice (eg NPSA).
6. Periodically review patient's condition and medication need at agreed intervals.
7. Communicate promptly with the GP in writing when to adjust the dose, stop or change treatment.
8. Have a mechanism in place to receive rapid referral of a patient in the event of deteriorating clinical condition.
9. Ensure that clear backup arrangements exist for GPs to obtain advice and support.
10. Report adverse events to the MHRA and GP.

General Practitioner responsibilities

1. Reply to the request for shared care as soon as practicable.
2. Prescribe [AMBER1MEDICINENAME] at the dose and regime recommended, and concomitant medication as directed.
3. Comply with terms of Local Enhanced Service Contract and any national advice on [AMBER1MEDICINENAME].
4. Arrange and monitor blood test results and response to [AMBER1MEDICINENAME] (where monitoring undertaken by GP).
5. Monitor the patient's overall health and well-being when patient presents and at intervals agreed with specialist.
6. Consult promptly with the specialist when test results are abnormal and when patient defaults from blood test appointments (where monitoring undertaken by GP); adjust the dose or stop or change treatment as advised by the specialist.
7. Stop treatment immediately if an urgent need arises and consult with specialist.
8. Check compatibility with other or new concomitant medication (eg computer-generated warnings).
9. Periodically remind patient of treatment regime, and which warning symptoms to report.
10. Report adverse events to the specialist and MHRA.

Patient's role

1. Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
2. Share any concerns about treatment with [AMBER1MEDICINENAME].
3. Inform specialist or GP of any other medication being taken, including over-the-counter products or herbal remedies.
4. Do not miss any blood tests or other appointments without first consulting the GP or specialist.
5. Report any adverse effects or warning symptoms to the GP or specialist.
6. Report any suspected pregnancy of the patient or partner to the GP or specialist.
7. Consume alcohol only in moderate amounts unless the specialist has advised that alcohol should be avoided.

Safety net : In the event of an emergency, care will revert back to the specialist.

GP/Hospital Communication Network

Contact .. ☎	Fax	Email Address
Consultants		
Specialist Nurses (RSN)		
Pharmacy Department: Principal Medicines Information Pharmacist		

Appendix 3

[Specialty] SHARED CARE PROTOCOL FOR [Amber1MedicineName] – Monitoring & Advice Sheet

GP monitoring responsibilities

- Arrange testing and monitoring of [add details]
- Ensure patient is attending for blood tests by checking recent results are available and review results as below before issuing a repeat prescription. [amend details as necessary]
- Counsel patient, when he/she presents, for potentially serious or persistent side-effects: [insert details]
- Remind patient, when he/she presents, to [insert details if appropriate]

Monitoring instructions

- **Withhold dose and follow action as below:**

and seek advice!	
and seek URGENT advice!!	
MEDICAL EMERGENCY	

- **for any reason not listed above please discuss with the Hospital Consultant BEFORE stopping or withholding treatment, or altering a patient's blood test schedule.**

Additional advice

- insert details of key contraindications, drug interactions, NPSA alerts, management of particular scenarios etc

- At current prices, incl VAT, treatment for 28 days with [drag name] costs £x.xx

This information is not inclusive of all prescribing information and potential adverse effect