Coventry & Warwickshire
Area Prescribing Committee

Transfer of prescribing from secondary to primary care – Specialist drugs

This document is intended to outline the roles of clinicians with respect to the transfer of prescribing between secondary and primary care, the term "specialist drug", the concept of a specialist drugs list and the signalling system and also the role of the Coventry & Warwickshire Area Prescribing Committee (APC).

1. What is a "Specialist drug"?

A specialist drug can be defined as a medicine, which has significant pharmacological complexity and/or rarity of use to make the prescribing of the medicine relatively uncommon in the community. Patients for whom complex medicines are prescribed, may have particular complex monitoring requirements, which require specialist knowledge for the appropriate interpretation of results. In such circumstances, due consideration needs to be given to the settings and knowledge required by the professional to undertake the prescribing, monitoring and supply of the medicine, in order to ensure high quality patient care.

2. Clinical and legal responsibility

When a doctor issues a prescription for a medicinal product, including a specialist drug, the clinical and legal responsibility for the outcomes of treatment rests with that doctor. Even if one doctor prescribes a drug recommended by another (*e.g.* a GP prescribing at the request of a consultant) the clinical and legal responsibility still rests with the actual prescribing doctor – **in case of an adverse event, it will be the prescribing doctor who will be held liable in the first instance.**

In hospitals prescribing of specialist drugs can occur in a well-controlled setting:

- The doctors are specialised and so have a thorough knowledge of drugs used within their specialities
- Careful monitoring of treatment is possible
- If a serious adverse event occurs in the course of a treatment, remedial action can be taken promptly

As a result of the above factors, the risk involved in prescribing new drugs, complex treatments or unlicensed drugs within a hospital setting is reduced significantly. Clearly it is not feasible to attain the same level of risk management in prescribing in general practice and so it is important that all those concerned understand these issues when colleagues in general practice are asked to assume responsibility for prescribing. For that reason a formal system of classifying specialist drugs

according to their suitability for primary care prescription has become custom and practice across most health economies.

3. System of transferring prescribing from secondary to primary care

Signalling system

Based on regional and national guidance, e.g. MTRAC and NICE, and discussions at the APC, drugs will be conveniently divided into the following categories – note that each category has conditions tied to it to enable safe and responsible prescribing across both secondary and primary care;

Category	Definition
SO	**Specialist Only -** **These drugs are deemed to be not appropriate for prescribing by GPs** ***Specialists should <u>not</u> ask GPs to prescribe these drugs***
SC	**Shared Care -** Responsibility for prescribing may be transferred from secondary to primary care with the agreement of an individual GP and when agreed shared care arrangements have been established. *The specialist MUST stabilize the patient before asking for care to be transferred.* **Only specialists should initiate these drugs. Prescribing should be transferred to GPs according to an (Essential) Shared Care Agreement [(E)SCA]**
SI	**Specialist Initiation -** These drugs must be initiated, i.e. the first dose prescribed, by the specialist and then may be continued by the patient's GP following communication from the specialist
SA	**Specialist Advised –** Specialists may simply advise a patient's GP to initiate these drugs themselves after they have made an initial assessment

Note: *SA drugs can be initiated by the specialist according to patient need and also depending on local commissioning arrangements which may mandate, through the contract between provider and commissioner, that all SA drugs are treated as SI.*

Once a category has been established for all specialist drugs a list, the Specialist Drugs List (SDL) will be published by the APC to all relevant clinicians including specialists, GPs and non-medical prescribers. This will be updated every two months to coincide with APC meetings where decisions will be made on SDL amendments.

Role of the Coventry & Warwickshire Area Prescribing Committee

The Coventry & Warwickshire Area Prescribing Committee will be responsible for assessing firstly whether a new drug is a specialist drug and then into which category it will fall. The APC will also maintain the Coventry & Warwickshire specialist drugs list, making amendments as necessary when, for example, a drug becomes licensed for a new indication.

New drugs

Specialists should not ask GPs to prescribe new drugs that are not approved or have not been considered for general use by the APC.

Specialists wishing to use new drugs should follow the normal Trust procedures in order to seek approval but should not ask GPs to prescribe until a decision has been made by the APC as to its placement in the list. It will be the responsibility of the APC to classify the new drug according to the 'signalling system'.

Essential shared care protocols (ESCAs)

An ESCA is a document that covers pertinent issues around use of a particular drug, designated as shared care (SC), when responsibility for prescribing the drug for a patient is transferred from secondary to primary care. Although standard protocols may be prepared for routinely used drugs, there will always be instances when standard protocols are not available or even desirable (e.g. unlicensed prescribing, new drugs and where information is better provided for whole treatment rather than on single drug) and in such cases patient specific protocols need to be provided for GPs. An effective shared care prescribing protocol would need to cover the following issues (each protocol should have a CONCISE summary of essential points for reference by primary care staff, including nurses):

a. Setting the context for use of treatment
   - Licensed status of drug
   - Indication for drug and reason for choice
   - Patient's condition at the time of transfer and what can be expected with continued treatment (prescribing should be transferred only if a patient has been stabilised on treatment; GPs cannot be expected to carry out frequent and complex dosage changes)
   - Patient's awareness of treatment (patient should have been counselled about the treatment and his or her consent obtained before GP takes over prescribing)

b. Monitoring requirements – consultant
   - What will the consultant monitor, how frequently and how will this be reported

c. Monitoring requirements – GP
   - What will the GP monitor, how frequently, where and how should this be reported and what immediate action may be necessary

d. Adverse reactions and management of adverse reactions
   - Although attaching a SPC on drug is fine, it is important to highlight the most serious or frequent adverse effects and how these can be recognised and what action to take if these effects occur

e. Criteria for stopping treatment

- As well as specifying the criteria it is important to state who will make the decision to stop the treatment, how should the treatment be discontinued and who will be responsible for counselling the patient

f. Communications
   - GP needs a contact point (telephone number, fax and/or email) both for routine enquiries and emergencies
   - The patient needs to know who to contact, when and how should they have a query

All parties should be satisfied with the shared care prescribing protocol before prescribing is transferred to the GP. It is quite appropriate for a GP to request an amendment to the protocol if he or she is not satisfied with any of the information.

The overall responsibility for producing an ESCA lies with the consultant. The APC will publish a set of standard ESCAs for all amber drugs in the specialist drugs list.

Financial implications

Financial responsibility should follow prescribing responsibility. This would mean that the Acute Trust would be responsible for the total cost of red drugs and the initiation cost of all amber drugs, and the PCT would be responsible for maintenance cost of all amber drugs. The cost impact of red and all amber drugs should be built into the hospital's services and financial framework and thus there should be no need for any transfer of monies from primary to secondary care.

The annual uplift in PCT's prescribing budget is supposed to cover the cost of all amber drugs. Practice budgets will be adjusted for 'high cost' amber drugs. Practices that decide to prescribe red drugs would have to fund the cost of red drugs from their own budgets.

Version 2.1.1
May 2013