

Availability of New Drugs – General Principles

Introduction

NHS Boards should have in place a policy for the managed entry of new medicines which sets out the local process and decision making arrangements, including exceptional prescribing (more detail on the principles for exceptional prescribing are attached) The overall aims are to provide assurance that those who need a medicine which has demonstrable benefits are receiving the most appropriate treatment for their specific circumstances; and to ensure there is consistency of approach across NHS Boards, while providing flexibility to ensure the arrangements reflect local circumstances.

In doing so, it is necessary to ensure that all healthcare professionals understand local policies and procedures for the managed entry of new, licensed medicines; and that there is a fair and consistent process for patients to enable equitable access to new medicines on the basis of clinical need.

Local decisions must ensure that advice from the Scottish Medicines Consortium and NHS Quality Improvement Scotland regarding NICE Multiple Technology Appraisals are fully reflected in local arrangements. In addition it is necessary to ensure that there is a fair, consistent and systematic process for requests for medicines to be prescribed on a case by case basis for individual patients; as well as arrangements regarding an appeals process to challenge decisions regarding access to medication within NHS Boards.

Key Features of Local Decision Making Arrangements

- NHS Boards should have a written policy which describes the systems and processes for the managed entry of newly licensed medicines. These policies should demonstrate clear links to wider board governance and accountability arrangements. There should be a description of the basis on which decisions are made including the constitution of any panels or committees; the timeframe for decisions; a description of the authority on which decisions can be made; arrangements for dealing with emerging evidence; and how local arrangements reconcile with arrangements for tertiary level services or services provided outside of the Board's area. There should be a description of how decisions will be communicated and the timescales which will apply.
- NHS Boards should make information describing the arrangements for consideration of new drugs publicly available together with the opportunities participation. There should be clearly identifiable links with NHS Board's patient focus public involvement arrangements.
- NHS Boards should ensure that an appropriately trained liaison officer is available to provide information to patients and the public regarding these arrangements.

- Decision making processes with regard to new drugs; and for decisions for individual patients should be part of the NHS Board's corporate and clinical governance arrangements. The transparency of these arrangements should be assured by NHS Board.
- NHS Boards should have arrangements in place and information available regarding situations where patients are treated in tertiary or specialist centres (including services organised on a regional or national basis) or outside of the NHS Board's area.
- NHS Boards should maintain an overview of the effectiveness of the arrangements for the introduction of new drugs.
- NHS Boards should identify and share good practice regarding arrangements for new drugs. Such an approach should also be adopted across clinical networks or for services provided at regional or national level. The Scottish Government will facilitate the sharing of models of good practice and ensure arrangements are in place to help NHS Boards to work collaboratively in the development of their arrangements in order to promote consistency of approach across Scotland

SPECIFIC GUIDANCE ON ARRANGEMENTS FOR EXCEPTIONAL PRESCRIBING

- NHS Boards should have a written policy describing the arrangements for exceptional prescribing requests and the links to wider board governance arrangements. This should include a description of the basis on which requests will be considered including the constitution of any panels and arrangements for securing expert advice and any new evidence. Arrangements for any appeals should also be included.
- NHS Boards should provide information to patients, families, carers and their representatives describing the arrangements for consideration of exceptional prescribing requests and the opportunities to participate in the process. There should be clearly identifiable links with NHS Board's patient focus public involvement arrangements.
- NHS Boards should ensure that an appropriately trained liaison officer is available to support the patient through the exceptional prescribing process.
- NHS Boards should ensure that all clinicians who may be involved in the exceptional prescribing process are aware of the policy for exceptional prescribing.
- NHS Boards should ensure that clinicians responsible for a patient's care instigate requests for exceptional prescribing on the basis of the patient's clinical needs and in accordance with the NHS Board's policy.
- The timescales for the decision-making process should be in accordance with the patient's clinical needs and communicated to the patient by the clinician responsible for the patient's care following discussion with those involved in dealing with the request. There should be no undue delays, with the process being conducted as quickly as is appropriate in line with the patient's clinical needs, while ensuring sufficient time for proper consideration of the case.
- The patient should be informed of the timescale for the decision-making process, how and when they will be informed of the decision and how they will be supported throughout the process, including any appeals.
- Where it is clinically appropriate patients may be given the opportunity to participate in the process. However, the arrangements should ensure the application can be considered on the basis of free and frank discussion by the clinicians involved.
- There should be appropriate record keeping arrangements in place including records on decisions reached and the outcome of any appeal.
- Support and information should be provided to the patient regarding their options following any decisions including appeals.

- NHS Boards should have arrangements in place and information available regarding situations where patients are treated in tertiary or specialist centres (including services organised on a regional or national basis) or outside of the NHS Board's area.
- NHS Boards should identify and share good practice regarding the handling of exceptional prescribing requests.