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The Scottish Government

Dear Colleague

IMPLEMENTING CEL 17 (2010): INTRODUCTION AND AVAILABILITY OF NEWLY LICENSED MEDICINES IN THE NHS IN SCOTLAND – GOOD PRACTICE GUIDANCE FOR NHS BOARD MANAGEMENT OF INDIVIDUAL PATIENT TREATMENT REQUESTS (IPTRs)

Introduction

This CMO letter provides consensus-based good practice guidance in relation to NHS Board management of Individual Patient Treatment Requests (IPTRs) as part of the implementation of CEL (2010) 17 entitled "Introduction and Availability of Newly Licensed Medicines in the NHS in Scotland"[1].

CEL (2010) 17 expected NHS Boards to have their local written policies for the introduction of newly licensed medicines fully operational by 1 April 2011.

Purpose

The key purpose of the guidance is to provide a framework within which NHS Boards should, as a matter of good practice, operate when dealing with requests for medicines, which have been appraised within their licensed indication by the Scottish Medicines Consortium (SMC) or NHS Quality Improvement Scotland (NHS QIS)[2], but have not been recommended for use within NHSScotland.

The framework is designed to achieve consistency of approach across all NHS Boards in Scotland in relation to management of IPTR requests for such medicines for individual patients.

The guidance:

- sets out the circumstances under which IPTRs will be considered;

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18 March 2011

SGHD/CMO(2011)3

Addresses
For action

NHS Board Chief Executives
Special NHS Board Chief Executives
NHS Board Directors of Public Health
NHS Board Medical Directors
NHS Board Directors of Pharmacy
NHS Board Chairs of Area Drug and Therapeutics Committees
NHS Board Exceptional Prescribing Leads
Regional Cancer Network Managers, Network Lead Clinicians and Pharmacy Leads

For information

Chair, Scottish Medicines Consortium
Chief Executive, NHS Quality Improvement Scotland
Area Clinical Forum Chairs

[1] http://www.sehd.scot.nhs.uk/mels/CEL2010_17.pdf

[2] NHS Quality Improvement Scotland will become Healthcare Improvement Scotland effective from 1 April 2011.

- reminds NHS Boards of their responsibilities in ensuring their written policy on IPTRs adheres to relevant legislation and national guidance – particularly around the provision of information for the public and patients;
- reminds NHS Boards of the need to secure patient and public involvement in the development of their local policies and processes in relation to IPTRs;
- sets out suggested referral criteria for IPTRs and appeals;
- identifies the key areas of expertise to be represented on decision-making and appeals panels;
- sets out suggested evidence on which IPTR and appeals decisions should be based;
- reminds NHS Boards about the need to facilitate timely and appropriate communication of decisions and the need to establish appropriate local systems to provide further advice and support to patients, their carers and families;
- reminds NHS Boards of the need to maintain accurate records regarding IPTR decisions and appeals; and
- identifies the need to link the IPTR process to the wider NHS Board governance arrangements.

How to use the Guidance

The guidance reflects consensus reached at the national seminar hosted by the Scottish Medicines Consortium on 11 May 2010 which identified the need for further national work to develop good practice guidance that NHS Boards should seek to apply when dealing with IPTRs. It also reflects feedback received from NHS Boards following circulation of the draft guidance on 5 January 2011.

The guidance provides a framework to support local decision-making on IPTRs through a consistent approach. Decisions regarding the provision of NHS services remain matters for NHS Boards; and clinicians remain responsible for clinical decisions regarding the care of individual patients.

The guidance comprises a main body document and an Annex.

Actions for NHS Boards

NHS Boards should seek to ensure that extant local policies, including those on IPTRs, have been impact assessed. As stated in CEL (2010) 17, NHS Boards are asked to ensure their local policies are closely aligned to the guidance by 1 April 2011. NHS Boards are further asked to confirm, by 1 April 2011, that they have robust systems in place to collate core data in relation to IPTRs, including the need to be able to produce summary management in confidence information to the Scottish Government on request. This guidance will be reviewed by the end of 2013, or earlier if required.

Yours sincerely

Harry Burns

HARRY BURNS

Good Practice Guidance for NHS Boards Management of Individual Patient Treatment Requests (IPTRs)

Overview

1. The IPTR process is designed to provide an opportunity for clinicians[3] to pursue, on a "case by case" basis for individual patients, a medicine that has not been accepted by the SMC or NHS Quality Improvement Scotland (NHS QIS) following their appraisal on clinical and cost-effectiveness.

2. Annex D of CEL 17 (2010) outlined a specific framework for the development of NHS Board written policies for individual patient treatment requests (IPTRs). This guidance seeks to go further to set out the key components of the process that NHS Boards should, as a matter of good practice, seek to apply in accordance with local circumstances.

3. Where NHS Boards have agreed to work together on tertiary services provision, or for any other reason, agreement should be reached on the application of IPTRs and appeals panels in these circumstances. The NHS Board written policy, together with any supplementary information available to the public and patients, is expected to reflect these arrangements.

Circumstances under which IPTRs will be Considered

4. IPTRs can only be sought for a medicine within its licensed indication for the condition in question and can only be pursued where the clinician fully supports the request. The IPTR process does not cover unlicensed or off label medicine use.

[3] The clinician is the hospital consultant or General Practitioner with overall clinical responsibility for the patient

5. An IPTR for a new medicine may be made when:

(i) the SMC or NHS QIS has issued "not recommended" advice for the medicine, including medicines not recommended by SMC due to company non-submission;

(ii) the request relates to use of the medicine outwith an SMC restriction; or

(iii) before SMC or NHS QIS has issued advice on the medicine – see Explanatory Note 1.

Explanatory Note 1

IPTRs should not be used to circumvent established assessment processes.

Where no SMC/NHSQIS advice is yet available but is awaited, the policy position across Scotland is that a medicine would not be expected to be routinely prescribed.

However, NHS Boards may wish to consider IPTRs in these circumstances where the clinician responsible for the patient believes a delay in treatment pending SMC/NHS QIS advice would result in a significant adverse outcome for the patient.

Information for the Public and Patients about the IPTR Process

6. Further to publication of the written policy on IPTRs, NHS Boards should make available to the public and to individual patients who have requested an IPTR, information on their IPTR arrangements in accordance with relevant legislation including Equalities legislation[4] . In doing so, NHS Boards should, as a matter of good practice, ensure that such information is fully accessible in easy read version and is available via different formats if

[4] http://www.scotland.gov.uk/Topics/People/Equality/18507/legislation

requested. The content could include (but is not restricted to) the following:

(i) clarification around what constitutes an IPTR in the context of local medicines management and decision making;

(ii) how, when and by whom, an IPTR can be initiated;

(iii) details of sources of local advice in relation to the IPTR process;

(iv) a description of who will consider IPTR requests;

(v) clarity on the basis on which IPTR decisions will be reached, and how, when and by whom supporting evidence/information can be submitted;

(vi) the timescales of decision making for IPTRs;

(vii) the timescales and methods for communicating decisions to patients/carers/patient advocates for whom an IPTR has been made;

(viii) information about the options open to patients when IPTR decisions have been reached, including information about the grounds on which an appeal can be made, how such appeals can be made, where local advice on appeals can be sought, information about the appeals process, timescales and communication of outcomes.

7. Where patients are going through the IPTR process, they should be signposted to a named individual appointed by the Board to provide information, advice and support. NHS Boards will wish to decide whether this is the clinician responsible for the patient's care or another named person.

8. However Boards define this role, it is important that a patient has a named individual (who may involve colleagues with additional skills depending on the patient's needs) and their contact details from whom to seek advice

and support. NHS Boards should ensure there are adequate arrangements in place to accommodate situations when the individual in question is not available.

Patient and Public Involvement in IPTRs

9. NHS Boards should secure patient and public involvement in the development of their IPTR policies and processes through their patient focus and public involvement arrangements.

10. In addressing patient and public involvement in IPTRs, NHS Boards should consider the following:

(i) the patient (or patient representative) involvement should be through discussion with the requesting clinician who will present the case for medicine use as part of the IPTR and will represent the patient's interests;

(ii) patients (or patient representatives) who wish to and are able to make a statement to the panel, should be advised that they can do so;

(iii) however, patients or representatives should not feel under any pressure to do so and the absence of such a statement will not present a disadvantage. Such statements are not a necessary addition to the information to be considered by the panel and will not form part of the evidence.

(iv) providing copies of IPTR documentation that will be made available to the decision-making panel considering the request.

Referral Criteria for IPTRs

11. The responsibility for an application for an IPTR rests with the clinician who supports prescribing the requested medicine. It is the clinician who is expected to demonstrate the clinical case for the patient to be prescribed a medicine within its licensed indication(s) where the following criteria apply:

> The patient's clinical circumstances (condition and characteristics) are significantly[5] different from either:
>
> (i) the general population of patients covered by the medicine's licence; or
>
> (ii) the population of patients included in the clinical trials for the medicine's licensed indication as appraised .

12. These circumstances imply that the patient is likely to gain significantly more benefit from the medicine than would normally be expected. Such considerations should be taken on a "case by case" basis reflecting clinical opinion and, as such, should not be generalised.

Consideration of IPTRs

13. CEL 17 (2010) clarified that NHS Boards are expected to include within their written policies, the constitution of decision-making panels for IPTRs. The choice of individuals invited to participate in IPTR decision-making is likely to be dependent on the medicine being requested. NHS Boards need to ensure some degree of flexibility to decide how best to manage this process within the timescales required – particularly when timing of a decision is crucial to the patient's clinical circumstances.

[5] It is for the clinician to assess whether the circumstances of the patient seeking the medicine would meet this criteria

14. In establishing an IPTR panel, NHS Boards should ensure that appropriate senior medical, pharmaceutical and managerial perspectives (including finance) are represented and should inform the patient/patient representative of the composition of the panel beforehand.

15. The individuals involved in IPTRs should be fully conversant with the NHS Board policies on the managed entry of newly licensed medicines. NHS Boards should give due consideration to any training required for panel members.

16. NHS Boards should also ensure that the members of IPTR panels are aware of their responsibilities in relation to declaration of any interests which could potentially impact on their impartiality in decision-making.

IPTR Evidence to be Considered[6]

17. IPTR decisions should be based on a range of evidence including:

(i) SMC/NHS QIS advice where available;

(ii) the referral criteria; and

(iii) the IPTR Case Report from the requesting clinician which will comprise:

- the rationale for the IPTR request including patient treatment history, prognosis and specific clinical characteristics;
- information on expected response and benefit;
- consequences of not using the treatment from both a patient and service perspective;

[6] NHS Boards may wish to have regard to the principles outlined in the *Making Difficult Decisions in NHS Boards in Scotland* http://www.nhshealthquality.org/nhsqis/7879.html

- consequences of using the treatment; and

- any other relevant information such as case reports, further evidence from literature reviews.

Timescales for IPTR Decisions

18. CEL 17 (2010) stated that "timescales for the decision-making process will be established in accordance with the patient's clinical needs and be communicated to the patient by the clinician responsible for the patient's care, following discussion with those involved in dealing with the request". Therefore NHS Boards should undertake preliminary examination of the request and ensure that due consideration is given to the urgency of the request given the patient's clinical condition and manage accordingly.

Communicating IPTR Decisions

19. On reaching a decision, a note of the IPTR decision should be provided to the requesting clinician.

20. IPTR decisions should be communicated to the patient/patient representative by the clinician responsible for their care. There should be an accompanying letter from the individual who chaired the IPTR appraisal to provide a brief summary of the rationale for the decision and to set out the circumstances under which an appeal can be made.

21. The clinician responsible for the patient's care should discuss the outcome of the IPTR request in detail, and clarify the options open to the patient for their future treatment. Where the patients feel they have grounds for appeal (as set out in paragraph 23), it is open to them to pursue this. Additionally, where the patient is not satisfied with the way the IPTR was handled, this could include progressing their concerns via the NHS complaints

process. Complaints and appeals about the IPTR can be progressed simultaneously and will not impact on each other.

Provision of Advice and Support Following IPTR Decision

22. Where appropriate, the clinician should provide the contact details of suitably trained personnel within the NHS Board who can provide further advice and support to the patient/patient representative and could include the provision of Independent Advice and Support Service[7] and/or any other patient information and support mechanisms available.

IPTR Appeals

23. There should be an appeals process in place for IPTRs. The appeals process is expected to accommodate appeals on either of the following grounds:

- The NHS Board has failed to act fairly (this would be where it was felt that due process had not been followed);

- The NHS Board has reached a decision which cannot be justified in light of the evidence submitted.

24. An appeal should not be accepted solely because the patient or the clinician does not agree with the views or conclusions reached. However, an appeal can be made where the patient and the clinician consider that the conclusion reached cannot reasonably be justified, in line with the available evidence. The appeal panel should review the IPTR panel's decision on this basis.

Explanatory Note 2: Where new evidence for the medicine emerges or if the original decision was based on a factual inaccuracy, this should not routinely be considered as part of an appeal but a resubmission through the initial process. Such considerations should not contribute to a delay in reaching IPTR decisions.

Referral criteria for IPTR Appeal Panel

25. An appeal can be referred where the clinician supports his/her patient's decision to appeal under the terms described in para 23.

Core Composition of IPTR Appeal Panel

26. The Appeal Panel should be established quickly to facilitate a timely review in accordance with the patient's clinical circumstances. It should not include individuals who were involved in the original consideration of the IPTR. Its composition is expected to include the relevant expertise to review the original process and decision and reach an independent conclusion.

27. The appeal panel could seek evidence from the clinician who supported the IPTR request and appeal but this person would not have a role in the appeal decision.

Evidence to be considered by the ITPR Appeal Panel

28. The IPTR appeals panel are expected to consider the following evidence:

- NHS board policy on IPTRs;
- The written evidence submitted in respect of the IPTR; and
- The written account of the rationale for the IPTR decision reached.

Communicating IPTR Appeals Decisions

29. On reaching a decision, a note of the IPTR appeal should be provided to the requesting clinician who should communicate it to the patient/patient representative. There should be an accompanying letter from the individual who chaired the Appeal Panel to provide a brief summary and rationale for the decision. This letter should signpost the patient/patient representative to an appropriate source of advice and support such as the Independent Advice and Support Service.

Monitoring

30. NHS Boards are expected to maintain accurate and up to date information on IPTR requests and the outcomes, including the outcome of any appeals, as set out in **Annex A**. These arrangements should facilitate requests from Scottish Ministers for summary information in relation to medicines requested and whether or not these were made available.

Links to NHS Board Governance Arrangements

30 The description of the process for an IPTR and its linkage to the wider Board governance arrangements is the subject of local agreement. The process and governance arrangements should be transparent and explicit and reflect the guidance laid out in CEL 17 (2010).

ANNEX A

IMPLEMENTING CEL 17 (2010) – MONITORING ARRANGEMENTS

Individual Patient Treatment (IPTR) request for [Medicine] to treat [Indication] for Patient [Identifier]

Date of Request:

Details of Clinician Supporting Request:
(Name, Job Title, Department)

IPTR Panel Composition:

Date of IPTR Panel:

IPTR Decision & Rationale:

Date Clinician/Patient/Carer Advised:

Details of Advice and Support Provided:

IPTR Appeal Requested? Yes/No

If yes, IPTR Appeal Panel Composition:

Date of IPTR Appeal Panel:

IPTR Appeal Decision and Rationale:

Date Clinician/Patient/Carer Advised

Management in Confidence Summary Information to be Made Available on Request

NHS Boards are asked to maintain accurate and up to date information on IPTR decisions; Appeals and their outcomes in order that the following information can be provided on request.

Date of Request	Medicine Requested	Indication	IPTR Panel Decision & Date	Appeal Decision & Date (where applicable)