5.2: POLICY FOR THE MANAGEMENT OF INDIVIDUAL PATIENT TREATMENT REQUESTS

IMPORTANT NOTE: This policy document is subject to review pending the introduction of the Peer Approval Clinical System which will shortly be introduced to replace Individual Patient Treatment Requests. This document should be read in conjunction with 5.2 Supplement: Interim Policy Statement: Individual Patient Treatment Requests (IPTRs) and Peer Approved Clinical Systems (PACS).

PURPOSE OF PAPER

This policy outlines the NHS GG&C management process of Individual Patient Treatment Requests (IPTRs) for medicines being used within their licensed indications when:

- The SMC or NHS HIS has yet to issue advice on the medicine
- The SMC or NHS HIS has issued "not recommended" advice for the medicine, including medicines not recommended by SMC due to company non-submission
- The request relates to the use of the medicine outwith an SMC restriction

Where no SMC/NHS HIS advice is yet available but is awaited, the policy position in NHS GG&C is that a medicine is not expected to be routinely prescribed. However an IPTR may be considered in this timeframe where the clinician responsible for the patient believes a delay in treatment pending SMC/NHS HIS advice would result in a significant adverse outcome for the patient.

BACKGROUND

Standardised non-Formulary processes were introduced to all acute sites in NHS Greater Glasgow and Clyde in 2008. The processes were then amended in 2010/2011 to reflect guidance from the Scottish Government (CEL (2010)17 and CMO (2011)3) regarding the introduction and availability of newly licensed medicines. Non-Formulary requests for medicines in the above categories were renamed Individual Patient Treatment Requests.

OVERVIEW OF IPTR AND NON-FORMULARY PROCESS IN THE ACUTE SECTOR

The purpose of completing an Individual Patient Treatment Request is three-fold:

- to act as a prompt to the prescriber to highlight the non-Formulary status and reflect on whether the choice is appropriate and whether the referral criteria for an IPTR have been met,
- to provide NHS GG&C with background information about the origins and reasons of non-Formulary prescribing of specific medicines, particularly those that have not been accepted for use in NHS Scotland by the Scottish Medicines Consortium
- to ensure that Directorate structures are aware and involved in the decision to use non-Formulary medicines.

The IPTR policy is applicable to all directly provided NHS GG&C services and its intention is to ensure a fair and consistent approach for all patients referred to NHS GG&C clinicians for treatment regardless of originating Health Board.

There are three categories of non-Formulary medicines, and the process for each of them differs as outlined below.

a. LEVEL 1

- IPTRs are not required for level 1 non-Formulary medicines, as to complete documentation for all these requests would prove time consuming and potentially lead to unnecessary delays in patient treatment.
- Level 1 non-Formulary medicines are typically those that pre-date SMC or NHS HIS advice and are usually prescribed in low levels at low cost. They can be supplied without the completion of any IPTR documentation.

b. LEVEL 2

- A list of medicines, including those not accepted for use by the SMC or awaiting evaluation has been developed (known as the IPTR List). This list details medicines that are designated as level 2 or level 3. For medicines or indications on this list designated as level 2, Form IPTR 2 will need to be completed by the nurse in charge of ward, the prescriber or pharmacy staff when a supply is required to be made by pharmacy.
- Where a non-Formulary medicine has been prescribed but a supply is not being made (for example, when the patient has their own supply of the medicine), there is no need to complete a form.

c. LEVEL 3

- Those medicines or indications which are not recommended for use by SMC or NHS HIS or are awaiting evaluation and where there are substantial cost or service implications associated with prescribing are designated as level 3. Generally, these medicines are specialist in nature with a cost per patient treatment in excess of £3,000 (or £3,000 per patient per annum for continuing treatment),
- These medicines or indications require the completion of an Individual Patient Treatment Request (Form IPTR 3) by the requesting consultant and will require approval by an IPTR Directorate Panel prior to a supply being made.

REQUESTS FOR MEDICINES NOT INCLUDED IN THE IPTR LIST

- Though the IPTR List is updated regularly, not all situations where the completion of an IPTR is required can be shown on this list. This includes medicines that may have been recently licensed and/or considered by SMC since the IPTR List was last updated,
- In circumstances where there is uncertainty, the Formulary & Handbook Team should be approached for specific advice (contact the team on (0141) 211 5433 or via the Medicines Information email address: ng.medinfo@ggc.scot.nhs.uk).

PROCESS FOR REVIEWING LEVEL 3 IPTRS

The process for reviewing a Level 3 IPTR for a medicine, indication or formulation that is not recommended for use or awaiting evaluation by the Scottish Medicines Consortium (SMC) or NHS HIS is detailed below. The aim is to ensure a consistent approach for all patients throughout the health board in accordance with guidance from The Scottish Government (as detailed in CEL(2010)17 and CMO(2011)3).

1. PANEL MEMBERSHIP

The Panel for reviewing a request for an Individual Patient Treatment Request (IPTR) will typically consist of:

- The Associate Medical Director for the relevant directorate (or nominated deputy)
- The General Manager for the relevant directorate (or nominated deputy)
- Senior pharmacist
- Senior medical representative, with specialist knowledge of the medicine / condition

All participants will complete a Declarations of Interest form for the record

In some circumstances it may be appropriate for Panel discussion and decision-making to be conducted remotely without the need to meet, however in all cases relevant interests should be declared and recorded.

The roles of the Panel members will differ in relation to their position:

- The Associate Medical Director (AMD) will act as chair and will consider the views of the other Panel members before seeking (typically) a consensual decision or (rarely) a majority decision on the request. Should there be a split decision, then the AMD has the casting vote

- The General Manager has a role to specifically consider the service issues of the request including consideration for the current and future implications on the budget and service.
- The role of the specialist medical adviser is described in 5.2.2. He/she will inform the Panel from the perspective of his/her clinical experience with the medicine / condition.
- The senior pharmacist will facilitate an overview of the clinical evidence and ensure alignment with due process (see 5.2.3 Briefing Notes for Lead Clinical Pharmacists Supporting IPTR Panels)

2. SUPPORT FOR IPTR PANELS

A Specialist Advisor (usually a specialist clinician) may be required to support the IPTR Panel and will primarily contribute a clinical perspective on the merits of the application (see 5.2.2 Briefing Notes for Specialist Advisors Supporting IPTR Panels)

3. REFERRAL CRITERIA

An IPTR can only be submitted when the clinician fully supports the request. The referral criteria for an IPTR should relate to the clinical circumstances (condition and characteristics) of an individual patient.

Cases referred to the IPTR Panel should seek to demonstrate the following criteria:

- That the patient's clinical circumstances (condition and characteristics) are significantly different from either:
  - The general population of patients covered by the medicine's licence (for medicines awaiting evaluation or non-submissions to SMC); or
  - The population of patients included in the clinical trials for the medicine's licensed indication as appraised by the SMC or NHS HIS

AND

- That these circumstances imply that the patient is likely to gain significantly more benefit from the medicine than would normally be expected.

Where SMC/NHS HIS advice is not yet available and therefore there is no clinical and cost effectiveness assessment, the policy position in NHS GG&C is that the medicine should not be prescribed. Where the IPTR has been initiated in this circumstance the Panel should consider whether there is an alternative treatment available and whether a delay in treatment pending SMC/NHS HIS advice would result in significant adverse outcome for the patient.

4. COMMUNICATION WITH THE PATIENT

(Also see section 5.2.1 Briefing Notes for Consultants submitting an IPTR)

The patient is supported and guided through the IPTR process primarily by his/her consultant, who will outline the terms on which an IPTR can be submitted and the basis of the case for the IPTR in addition to answering any specific questions the patient may have. The patient is also supported by other means including:

- Patient Information Leaflet: This outlines the IPTR process and appeals process in NHS GG&C in terms that can be easily comprehended by most patients and answers the most frequently asked questions (see 5.2.4 Patient Information Leaflet: Access to New Medicines in the NHS)
- Access to other persons within the Health Board who can offer support regarding the IPTR process (via the patient's consultant)

5. APPLICATION FOR PATIENTS RESIDING OUTWITH NHS GG&C

The West of Scotland Health Boards have agreement on the management of IPTRs within each others' Boards. The host Board is the one to which the patient has been referred from a home Board. The host Board (in this case NHSGG&C) and the host Board's Clinician assume responsibility for the patient's care. Two separate mechanisms will be applied, dependent on the cost per patient treatment or cost per patient per annum for continuing treatment:

(a) < £25,000

The standard NHS GG&C procedures will apply, with notification of the decision to the Medical Director of the home Board (or nominee) at the conclusion of the Panel review

(b) ≥ £25,000
An invitation will be extended to the Medical Director of the home Board (or their nominee) to participate as a Panel Member with full voting rights.

The decision of NHS GG&C Panel will be final and not subject to a further review at home Board level.
Following receipt of a decision from an IPTR, the home Board has the opportunity of providing feedback to inform the process for future IPTR Panels.

Note: NHS Highland requires patients referred to NHS GG&C for treatment to submit any IPTR directly to NHS Highland for consideration. Details for the IPTR process in NHS Highland, including the documentation to be used, can be accessed via the NHS Highland website (www.nhshighland.scot.nhs.uk).

6. APPLICATION FOR PATIENTS REFERRED TO HEALTH BOARDS / TRUSTS OUTWITH NHS GG&C

In circumstances where a patient is referred to a clinician outwith NHS GG&C for advice, but the responsibility of prescribing remains with the local clinician, NHS GG&C Formulary processes will apply, including the completion of an IPTR application. This advice will form part of the evidence for consideration by the NHS GG&C Panel.

In circumstances where a patient is referred to a clinician outwith NHS GG&C for full clinical responsibility / supervision of care, then NHS GG&C will normally abide by the prescribing policies and decisions of the external Board / Trust, although completion of the NHS GG&C IPTR documentation is considered good practice for audit and financial control purposes.

7. TIMESCALE FOR DECISION

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. Upon receipt of an IPTR, in establishing an IPTR Panel, due consideration is given to the urgency of the request given the patient's clinical condition. A date should be set to review the IPTR and examine the evidence and advise the patient of the date accordingly. The aim is for the timescale between the receipt of the IPTR and a decision not to exceed 20 working days.

There may be cases where an IPTR is considered an emergency and there is not sufficient time to fulfil the formal process. In these cases, the Associate Medical Director (or nominated deputy) will be required to make a rapid assessment about the appropriateness of the request and approve the use of the medicine on a short-term basis to allow time for the full approval process to be completed. It should be understood that a decision to approve an IPTR in these circumstances will not imply a commitment to further prescribing when a full application and evaluation takes place. In such cases, the AMD will be supported by senior medical and pharmacy colleagues as required.

8. NATURE OF EVIDENCE

The onus is on the applicant to demonstrate that the referral criteria described in Section 3 are fulfilled and clearly described in a fully completed IPTR3 Form. The evidence that the Panel considers may include:

- SMC/NHS HIS advice and the detailed advice document (DAD) where available
- The referral criteria
- The IPTR case report from the requesting clinician which will comprise:
  a. The rationale for the IPTR request including patient treatment history, prognosis and specific clinical characteristics
  b. Information on expected response and benefit
  c. Consequences of not using the treatment from both a patient and service perspective
  d. Consequences of using the treatment, including cost, duration of treatment and stopping rules

e. Any other relevant information such as case reports and further evidence from literature reviews

- Patient /patient advocate statement

  If the patient is able and wishes, he / she can be given an opportunity to contribute to the evidence reviewed by the Panel by completing the appropriate section of the IPTR 3 form. This may be prepared by the patient or by a representative on his / her behalf. This will be presented in the knowledge that the IPTR decision will be based on clinical factors only and will take no account of the patient's social circumstances. Formal consent will be sought in the event of involvement of a patient representative.
- Declarations of interests, both of the clinician supporting the IPTR and the IPTR Panel.

In most cases the evidence provided by the clinician will be supplemented by an independent evidence briefing prepared by an appropriate clinical / medicines information pharmacist for consideration by the Panel. A template is available for this purpose (appendix 1)

The completed IPTR3 Form together with any supporting literature should be submitted to the relevant AMD who will initiate the review and circulate to the other Panel Members.

All supporting evidence, including any patient statement, should be submitted to the IPTR Panel to allow sufficient time for it to be circulated and evaluated by Panel members prior to the Panel hearing. Unless there are exceptional circumstances, this should be at least 3 working days prior to the Panel hearing. Flexibility on this timescale applies to patient statements in support of an IPTR, but these should not be submitted within 48 hours of the Panel hearing.

9. PANEL DECISION

The Panel will weigh up the evidence for the application in order to make their decision and will only approve those requests where the referral criteria have been fully met (Section 3). Where the request for the medicine is likely to impact on more than one directorate, it will be the responsibility of the Panel to liaise with other directorates as appropriate.

10. DOCUMENTATION AND COMMUNICATION OF DECISION

The decision of the Panel, along with any relevant supporting information or terms of use, will be recorded in full by the Panel on the relevant section of Form IPTR-REC. It is essential that any decision is documented carefully. This information should include a clear explanation and justification of the decision, dates of any meetings and full details of all those involved. A brief overview of the decision will also be noted in the relevant section of Form IPTR 3.

On reaching a decision, a written note of the IPTR outcome and a copy of Form IPTR-REC will be provided to the requesting clinician, by the IPTR Panel Chair. This will provide a brief summary of the rationale for the decision and will set out the circumstances under which an appeal can be made

The requesting clinician will then have the responsibility to communicate this decision to the patient or patient's representative. If positive, then the medicine can be prescribed on the NHS with immediate effect, dependent on the individual circumstances of the case. If negative, when discussing this outcome for the IPTR, the clinician should also clarify the options open to the patient for future treatment including the possibility of an appeal if there are grounds for this. The option to appeal (Section 5.3) is available to the clinician, in consultation with the patient, within 2 months of the IPTR decision.

A copy of the completed Form IPTR 3 and IPTR-REC, regardless of the outcome of the review, should be sent to the Lead Pharmacist for Formulary and Prescribing Interface. The AMD should retain a copy of all documents for their own records, which may help in the evaluation of future requests for the same medicine.

Data from the IPTR documentation will then be collated by the GG&C Formulary Team in a secure database complying with Scottish Government advice with IPTR data relating to specialist oncology being collated in a

separate similar database. A summary of all Level 3 IPTRs will be made available to the Acute Services Prescribing Management Group on a quarterly basis.

11. IPTR APPEAL

A consultant has the right to ask for a review of the process or decision applied to an IPTR declined at Directorate level (Section 5.3). Each appeal must be supported by relevant documentation. It is the aim that the appeal will be heard within 20 working days of submission, by a Review Panel of the Board Medical Director, the Head of the Pharmacy & Prescribing Support Unit (PPSU) or their nominees, a lay member, supported by a specialist advisor (if required). Their decision will be final. The Panel will be supported by the PMG Professional Secretariat (or nominee) as described in NHS GG&C 'Policies relating to management of medicines', Section 5.3 Individual Patient Treatment Request Appeal Process

12. REAPPLICATION THROUGH IPTR PROCESS

Should an IPTR and a subsequent IPTR Appeal be rejected, the options remaining to the patient, including the potential procurement of the requested medicine via a co-payment agreement (see 5.5 Policy for Patients to Receive Aspects of Their Treatment Through Private Healthcare Providers (Co-payments)) will be outlined by the patient's clinician.

If the medicine/indication/formulation subsequently becomes accepted for use within NHS Scotland through SMC or HIS, the individual case and appropriateness of the treatment will be re-evaluated by the patient's clinician.

Should new clinical evidence emerge for an individual case or there is a material change in the patient's condition that may impact on the outcome of the IPTR, application of a new IPTR at directorate level may be considered where the clinician is in support.

APPENDIX 1: INDIVIDUAL PATIENT TREATMENT REQUEST EVIDENCE BRIEFING

Individual Patient Treatment Request (IPTR) Evidence Briefing

Name of Medicine
Licensed Indication
Indication under review
SMC Status http://www.scottishmedicines.org.uk/Home
Other relevant national Advice
National Institute for Health and Clinical excellence (NICE) http://www.nice.org.uk/Guidance/TA/Published
All Wales Medicines Strategy Group (AWMSG) http://www.wales.nhs.uk/sites3/page.cfm?orgid=371&pid=24773
SIGN Guidelines http://www.sign.ac.uk/
Other professional guidelines Note 3
Dose and Administration

Background
Summary of evidence of comparative efficacy and adverse effects
Clinical Effectiveness
Health Economics
Cost
References
Search Strategy
Author's details

Completion Guidance

Note: Previously completed evidence reviews in response to IPTR requests are held in a central repository on the NHS Knowledge Network. Please contact your local Medicines Information Services to check whether a review has previously conducted for the medicine.

The following information should be included in an evidence briefing provided to support the IPTR process.

Name of Medicine
Generic name of the medicine

Licensed Indications
Relevant licensed indications as per Summary of Product Characteristics (SPC) in the electronic medicines compendium (eMC) http://www.medicines.org.uk/emc/. There is no need to include licensed indications not relevant to the submission.

Indication under review
A medicine may be licensed for a number of licensed indications which may be subject to differing SMC advice. Some submissions may be for off-label use of medicines. In some cases the submission may for an indication that is a subset of the licence (this may be defined as the case for exceptionality). It is helpful for the exact indication that is the subject of the application to be detailed here. This allows a comparison between the patient's specific indication and the licensed indication and also the indication on which SMC advice is based.

SMC Advice http://www.scottishmedicines.org.uk/Home
Relevant SMC advice for the medicine and indication under review should be described here. This can be taken directly from the Detailed Advice Document (DAD) on the SMC website.[Note 2] Whether the medicine is "not recommended" or "accepted for use" within specific restrictions should be described.

For recently launched medicines where no SMC advice is as yet available, the SMC work programme can provide an estimate of when advice will be available.

National Institute for Health and Clinical excellence (NICE) http://www.nice.org.uk/Guidance/TA/Published
The first page of NICE technology assessments published in the last 2-3 years **should** state on the front page whether they are STAs or MTAs. E.g. "This guidance was developed using the single technology appraisal process." However, this may not always be clear. The status of these TAs for NHS Scotland can be confirmed on the NHSQiS website. [Note 1] http://www.nhshealthquality.org/nhsqis/1816.140.144.html

MTAs
Multiple health technology assessments (MTAs) issued by NICE are reviewed by NHS Health Improvement Scotland (NHS HIS) who then give advice to NHS Boards about the status of these assessments within Scotland. Where issued, this guidance supersedes any existing SMC advice on the medicine

STAs
The process for NICE Single Technology Assessments (STAs) is broadly similar to that adopted by the SMC and as such STAs decisions have no standing in NHS Scotland. STA advice very rarely comes before or differs from that issued by the SMC but it can be useful to review NICE STAs to establish prescribing policy elsewhere in the UK.

MTAs relevant to NHS Scotland should be described in this section. In some cases it may also be helpful to detail advice from NHS to NHS England issued as an STA. Contact Medicines Information if you are in doubt about what information is relevant to provide.

All Wales Medicines Strategy Group (AWMSG) [Note 1]
http://www.wales.nhs.uk/sites3/page.cfm?orgid=371&pid=24773

As for NICE advice for NHS Engalnd, it may be helpful to describe advice on a medicine issued within Wales, particularly if that differs from SMC Advice or is available where no SMC advice exists.

SIGN http://www.sign.ac.uk/
For some medicines, particularly those used in chronic disease management, it may be appropriate to describe any relevant SIGN advice. It should be noted, however, that SIGN do not currently consider cost effectiveness when considering the evidence base for any medicine.

Other professional guidelines
Guidelines issued by relevant clinical or professional bodies that may influence the use of a medicine should be described. There is no comprehensive method of searching for these guidelines. Some may be archived within the NeLM website. Others may be picked up from general review articles on the topic. In some cases it may be necessary to search the website of any relevant professional bodies.

Dose and administration
This information should be documented as per eMC for the indication under review. If the medicine is to be used off label, information may be obtained from the pivotal clinical trials. Any information on administration that may impact on service delivery should be described.

Background
Depending on the nature of the condition, a brief summary of the disease being treated and its usual management may be helpful for the Panel, who are not likely to be specialists in the treatment of the disease and medicine under consideration.

Summary of evidence of comparative efficacy and adverse effects
Where SMC advice has been issued, it may only be necessary to refer to the Detailed Advice Document (DAD). [Note 2] However, where the clinician making the request has made the case that the patient's situation is "exceptional", it may be necessary to provide a more detailed review of the evidence surrounding this "niche" indication. This section may be very important to the decision making around whether there is evidence that the patient is likely to gain significantly more benefit from the medicine than would normally be expected.

Where no SMC, NICE or AWMSG advice is available a detailed independent review of the literature may be required.

Clinical Effectiveness
This section should include a comment on any relevant issues in relation to how the clinical efficacy data may translate into clinical practice. For example, the patient population within the trials may differ significantly from that encountered locally.

In addition, any wider policy issues in relation to how the medicine has been used elsewhere may be important. A comment on potential success criteria, monitoring and stopping rules should be considered.

Health Economics
Where SMC advice has been issued, relevant information from the Detailed Advice Document (DAD) should be detailed. [Note 2] In some Boards, specialist advice from health economists may be available. Where no SMC advice is available (or where the medicine is to be used in a different patient group than that reviewed by SMC) and specialist input is also unavailable, any relevant published health economic data may be described. In some cases NICE may have carried out health economic reviews of patient subgroups within the trials that may have relevance to the application. Rarely, relevant heath economics studies may be published in the medical literature (identifiable via a Embase® or Medline® search or from the Cochrane Library)

Cost
The NHS cost of the medicine should be included. This may be the cost for one month's treatment or one treatment course. For a medicine that is expected to be continued in Primary Care, the basic NHS cost as per the

BNF or MIMs should be used. For medicines to be prescribed in acute care only, the NHS hospital cost should be used. The cost of any consumables or sundries should also be considered where relevant.

References
The main references used in the preparation of the briefing should be included.

Search strategy
It is good practice to document the search strategy undertaken when preparing the briefing. It may be agreed locally that the search strategy is not included in the published briefing but is held in the archived copy for information.

Author's details
The name of the author, checker and the date written should be included in the document

Notes

1. The National Electronic Library for Medicines http://www.nelm.nhs.uk/en/ routinely publishes advice issued by SMC, NICE and AWMSG and may, therefore, be a quick link to the advice on specific medicines on these websites
2. The Detailed Advice Document is published by the Scottish Medicines Consortium for each of the medicines considered by its committees. It includes details of the medicine and indication reviewed, the advice to NHS boards and a clinical appraisal of the clinical and economic data submitted by the pharmaceutical company. It includes sections on: indications, dosing information, product availability date, comparative efficacy, comparative safety, clinical effectiveness, comparative health economics, relevant guidelines, previous SMC advice, comparative costs and budget impact.

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22nd March 2011; version 4