1. 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 medicine/indication have not yet been submitted to the SMC for evaluation
- The SMC has issued "not recommended" advice for the medicine/indication because the company have failed to make a submission to the SMC (non-submission)
- The SMC have issued advice on the medicine/indication, but the intended use of the medicine is outside the company positioning (selective submission) which was evaluated by the SMC.

The Peer Approved Clinical System, both Tier 1 and Tier 2, should be used for all other requests for licensed medicines that do not fall into the above situations. Guidance on which process to follow can be found on the GGC Medicines website.

This policy also incorporates guidance intended to introduce 'flexibility' into the IPTR process as outlined in *Access to Medicines – Transitional arrangements for processing individual patient treatment requests* (SGHD/CMO(2013)20)

2. Background

The Individual Patient Treatment Request (IPTR) process was introduced in 2010 to reflect guidance from Scottish Government (CEL (2010)17 and CMO (2011)3) regarding the introduction and availability of newly licensed medicines. In November 2013, following on from the New Medicines Review and additional guidance from Scottish Government (SGHD/CMO(2013)20), a replacement process (Peer Approval Clinical System (PACS)) was proposed.

3. Overview of IPTR and non-formulary process in the acute sector

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.

In NHS GG&C, the full IPTR process with review by a panel is only required for applications for applicable medicines where the basic NHS list price of the medicine exceeds £3,000 per patient treatment (or £3,000 per annum for continued or long-term treatment). This is to balance the resource required to implement IPTR against the benefit of a detailed process for low cost medicines. Medicines under this threshold will be subject to continuous review and management.

4. Process for reviewing IPTRs

The process for reviewing an IPTR for a medicine, indication or formulation that is not recommended for use or awaiting evaluation by the Scottish Medicines Consortium (SMC) 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, CMO(2011)3) and CMO(2013)20.

5. Panel Membership

The Panel for reviewing a request via IPTR will be clinician-led and will typically consist of:

- Senior physician (e.g. Chief of Medicine, Clinical Director, Medical Director) or nominated deputy
- Senior pharmacist

An appropriate person to comment on service requirements and implications (such as a General Manager or Service Manager) may be sought to join the panel where required

Local arrangements should be in place for managing IPTRs for patients from other health boards (see section 4).

6. Referral criteria and consideration by the IPTR panel

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

AND

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

These are clinical criteria which are assessed on a case-by-case basis. Affordability or cost is not considered as part of the assessment.

In relation to more recent advice from Scottish Government (CMO(2013)20), the panel will exercise additional flexibility via:

- The expectation that peer review will be incorporated as part of the evidence base e.g. an MDT report or the opinion of the Clinical Team Lead
- The option for the IPTR applicant (clinician) to contribute directly to the panel discussion
- The additional emphasis on 'peer approval' where the evidence is equivocal, where the panel decision is split or where reasonable doubt exists for rejection of the IPTR referral criteria.

Where SMC advice is not 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 routinely 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 advice would result in significant adverse outcome for the patient.

7. Communication with the patient

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
- Access to other persons within the Health Board who can offer support regarding the IPTR process (via the patient's consultant)

8. 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).

The agreement described above is only relevant to West of Scotland health boards. When an IPTR request for a patient from other health boards is received in NHS GG&C, the relevant board should be linked with to establish the agreed mechanism for considering the request

9. 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.

10. 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 Chief of Medicine (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.

11. 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 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.
- The incorporation of peer review into the evidence base, e.g. an MDT report or the opinion of the Clinical Team Lead.
- 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 CoM 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.

12. Private healthcare

Where a patient has used private treatment to access a medicine not routinely available in NHS Scotland, they are not expected to be eligible to apply for that medicine to be funded by the NHS via an IPTR during that episode of care. If an IPTR is being pursued, evidence from experience in the private sector can be submitted to support the application if it is an objective and scientific measurement of response. However, a demonstrable response is not necessarily an indicator that a patient will meet the criteria required for IPTR acceptance. This is in keeping with the principles laid down in the guidance to the NHS in Scotland and helps avoid the development of inequity in access to NHS services.

13. Panel decision

The Panel will weigh up the evidence for the application in order to make their decision, considering the applicability of the referral criteria and additional flexibility as outlined in 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.

14. 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 IPTR3. 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.

On reaching a decision, a written note of the IPTR outcome and a copy of the fully completed Form IPTR3 will be provided to the requesting clinician, by the IPTR Panel Chair. This will provide a brief summary of the rationale for the decision.

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 5.5) is available to the clinician, in consultation with the patient, within 2 months of the IPTR decision.

A copy of the completed Form IPTR3, 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 in a secure database complying with Scottish Government advice.

Where there is an expectation that a medicine being requested for use will be continued to be prescribed and supplied within primary care, it is the responsibility of the requesting clinician to ensure that the relevant prescriber in primary care is aware of the status of the request.

15. IPTR appeal

A consultant has the right to ask for a review of the process or decision applied to an IPTR declined at sector level (or in the case haemato-oncology, oncology or neurology at service level). For details of the IPTR Appeal process, see separate guidance.

16. 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 separate guidance) will be outlined by the patient's clinician.

If the medicine/indication/formulation subsequently becomes accepted for use within NHS Scotland through SMC, 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[1]
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
Dose and Administration
Background
Summary of evidence of comparative efficacy and adverse effects
Clinical Effectiveness
References
Author's details
Written by: Reviewed by: