A framework for the management of Individual Patient Treatment Requests (IPTR)

A. Overview

CEL 17 (2010) provides a national guidance for the managed introduction of new medicines in NHS Scotland. This framework sets out, as defined by the CEL, the referral criteria for IPTRs and appeals, panel membership, processes to be followed and evidence on which decisions should be based. It also provides details on decision making and reporting timeframes.

B. Regional Approach

A standard regional approach has been adopted in the West of Scotland for the principles of the IPTR process, with recognition of the need for local procedural variations.

Variations will reflect differences in scale, structure and staffing of the constituent Boards.

This framework recognises and is based on the regional framework developed by the West of Scotland Boards Director's of Pharmacy.

C. Eligibility for IPTR

The focus of attention should be within licensed indications only of medicines which are not recommended by SMC, whether as an outcome of review or of non-submission.

Consideration is therefore required on the differing implications for medicines which

- are not recommended post SMC review, whether as a result of good evidence or lack of evidence
- are not recommended due to non-submission, whether in the immediate post-marketing authorisation phase or following failure of the company to submit within a satisfactory timescale

Where urgency of clinical circumstances can be demonstrated, the IPTR decision may be reached before SMC advice has been given; it should be noted that this decision should not be seen as precedent setting.

The IPTR process does not cover unlicensed or off label medicine use.
D. **Home Board influence on Host Board IPTR decision**

It is recognised in a regional framework that some decisions will be required in a Board which is not the residential home of the patient. In this circumstance it is accepted that IPTR leadership and implementation should rest with the ‘Host Board’; however the ‘Home Board’ should have the right to membership of the IPTR Panel when a specified medicine cost threshold is exceeded (to be determined at a regional level). Panel membership for the Home Board in this circumstance constitutes full voting rights.

E. **Referral criteria**

The CEL indicates that an IPTR can only be pursued where the treating clinician fully supports the request, and the request does not cover unlicensed or off label use of the medicine.

The IPTR for a new medicine may be made

i) when the SMC or NHS QIS has issued ‘not recommended’ advice for the medicine, including medicines not recommended by SMC for non-submission

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

iii) prior to SMC or NHS QIS issuing advice on the medicine.

F. **Onus of responsibility**

The onus of responsibility rests with the treating clinician to demonstrate the clinical case for the individual patient, such that the following criteria are both satisfied:

- the patient’s clinical circumstances are significantly different from either:
  - the cohort of patients included in clinical trials considered by the SMC
  - the population of patients who meet the licensed indication

and

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

The treating clinician thereafter will act as the patients representative.

G. **Evidence gathering**

The principle is to ensure that high quality, relevant evidence pertinent to the patient’s clinical circumstances is presented to the IPTR panel. The primary responsibility for gathering this evidence lies with the applying clinician. They may be supported in doing this by an appropriate clinical pharmacist.

- A template is made available as an appendix to this document to guide, this will promote consistency in presentation of the evidence, irrespective of the medicine or clinical situation

- In this way, a database can be developed allowing NHS Boards to share previous ITPR experience and therefore reducing duplication of effort

It is clearly important to get each decision right 1sted time. This demands close attention to the process for the panel, the documentation, the evidence, the timescale, the patient perspective, the communications etc. To support the process, the following documentation has been developed:

- Template for collation of IPTR evidence (Appendix 1)
- Template for IPTR submission (Appendix 2)
- Template for record of IPTR decision (Appendix 3)
- Patient Information Leaflet on IPTR process (Appendix 4)
H. Evidence Register

A regional approach will be adopted to create an ‘IPTR Evidence Register’ (as above), as an internal NHS reference which will:

- Avoid repeated review of recurring IPTR scenarios
- Promote consistency of approach
- Improve the efficiency of decision making

Each entry in this register will focus on the evidence, providing a generic analysis in a consistent format (Appendix ) in a specific clinical indication. This in turn can inform decision making in individual patients.

It is also essential to acknowledge what this register will not hold:
- any patient identifiable data
- any IPTR outcomes

The latter is founded on the principle that each IPTR is unique. While there may be recurring scenarios (and clearly consistency is desirable), IPTR panels should judge each case on its individual merits.

I Data for the IPTR

There is a requirement to register any potential conflict of interests from all participants:

1. the applicant
2. any supporting Clinical Pharmacist(s)
3. the IPTR Panel members

For 1 and 2 this will be recorded on the template for IPTR submission and for 3 this will be recorded on the template for record of IPTR decision.

There should be 2 separate strands of evidence presented to the IPTR panel, namely:

- Evidence base
- Patient specific information

These will be presented in line with Appendix and will be the responsibility of the applying clinician who has raised the IPTR. It is hoped it will be possible to develop an on-line template for submission of the IPTR, to promote consistency of approach on a regional basis. This could prompt information about the patient in a series of mandatory fields. But currently the database does not exist.

If the patient is able and wishes, they can be given an opportunity to contribute to the evidence reviewed by the Panel, in the form of a brief written statement, 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. National guidance on the overall process from a patient perspective is available (Appendix 5 ) and a local information leaflet on the IPTR process has been prepared (Appendix 4 ) and will be available to applying clinicians who can pass this on to the relevant patient.
J. Panel evaluation process
The composition of the IPTR panel within NHS Dumfries and Galloway is as follows:
- Medical Director (Chairman)
- Chief Pharmacist (Vice Chairman)
- Head of Prescribing Management
- 2 x Hospital Consultants
- 2 X General Practitioners
- General manager / Accountant

The overall process will be consistent in every case and the audit trail of documentation, decision and communication will be clear.

In times of urgent clinical need, a ‘virtual panel’ may be established using the above membership, to obtain a rapid decision. Standard documentation will still be used in this scenario, and the creation of the virtual panel and its membership will be recorded.

K. IPTR Outcomes
Possible outcomes are illustrated in Appendix 6. The panel decision is binding. Approval paves the way for NHS treatment. Rejection puts the onus back on the applicant. He / she is entitled to appeal, either (a) on the basis that the IPTR process was flawed in some way or (b) on the grounds of re-evaluation of the clinical evidence. The latter should be differentiated from the emergence of new evidence which is sufficient to justify resubmission of the case to the original IPTR Panel.

In relation to (a), it is possible that
- relevant procedures were not followed
- relevant evidence was overlooked
- relevant personnel were not consulted
- agreed timescales were not adhered to
- communications were incomplete

In relation to (b), the applicant may believe that this medicine remains the only therapeutic option for the patient and that further review of the clinical evidence is necessary.

L. Appeal Panel
An appeal application should be submitted using the template attached in Appendix . If this documentation is complete and the grounds for the appeal are valid, then the Appeal Panel will be constituted to examine the IPTR (process and / or evidence, as above). The panel will be chaired by the Director of Public Health and will include 2 other medical members and 2 pharmacist members. No member will have been involved in any stage of the original process.

For patients being treated in a Board in which they are not resident, in line with the original IPTR, the Host Board manages the appeal with a Home Board representative to contribute to the decision making.

In summary:
Responsibilities
The Appeal Panel will consider whether:-

i. Proper procedures have been followed when considering the IPTR and whether

ii. All of the evidence presented to the IPTR Panel has been properly and fully considered; and whether

iii. The IPTR Panel came to a reasonable decision based on the above factors.
Evidence
The Appeal Panel will have all the documents available to the original IPTR Panel, as well as the record of the decision and reasoning.

The appellant is not permitted to introduce new or additional evidence to support the appeal. It is the responsibility of the IPTR Panel to review new or additional information as a resubmission.

The entire case may be received in writing by the Appeal Panel without representation from the original IPTR Panel or the applicant being present. If however if the Appeal Panel considers that it would be beneficial to have either side present to the hearing then the other side will be invited to present also.

Outcomes
The appeal panel will determine one whether the appeal is upheld or rejected.

Process:
- the original IPTR process was valid, therefore the appeal is rejected and there is no basis for treatment on the NHS. As highlighted in the CEL, the only other possible access to treatment is via the independent care sector
- the IPTR process was flawed, therefore the appeal is upheld and the case will return to the original IPTR panel for reconsideration

Evidence:
- the Appeal Panel concurs with the original IPTR Panel; the appeal is rejected, as above
- the Appeal Panel interprets the evidence differently and a conclusion is reached which recognises exceptionality; the appeal is upheld and the medicine can be prescribed on the NHS with immediate effect

M. Communications and timescales
All communication will be in writing, although this may be by email. If email access is problematic then verbal communication is acceptable but must always be followed up in writing.

The IPTR panel is scheduled to meet monthly and therefore each IPTR submission will be reviewed within a 1 month period. Feedback on each decision will be made within 10 working days to the applying clinician.

In the event of a negative outcome which is to be appealed, the appeal must be lodged within 28 days of receipt of feedback.

An appeal panel will meet within 1 months of receiving notice of appeal, and will inform the appellant of a decision within 10 working days.

N. Appendices
1. IPTR Evidence Briefing Template
2. Template for IPTR submission
3. IPTR decision record
4. Patient Information Leaflet on IPTR process
5. National guidance for patients on overall process for management of new medicines in NHS Scotland
6. IPTR: WoS process flowchart