## 1. Purpose of policy

This document outlines the NHS GG&C management process for the appeal of decisions relating to 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.

## 2. Criteria for appeal

The requesting clinician may appeal against the outcome of the IPTR panel on the basis of the criteria described below. A patient is unable to request an appeal of a declined IPTR unless he/she has the full support of their consultant, who would submit the appeal. Each appeal must be supported by relevant documentation (Section 6).

An appeal may be made, 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.

## 3. Panel Membership

The Panel membership consists of the Board's Medical Director, the Director of Pharmacy or nominees and the lay member. In addition to forming a view on the merits of the appeal and the exceptionality of the case, the role of the lay member is to facilitate a fair and transparent approach.

The Board's PMG Professional Secretariat should attend as observer and recorder. Some circumstances may demand the inclusion of an Expert Adviser to the Panel. This will be at the discretion of the Panel Chair.

## 4. Application to patients outwith NHS GG&C

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 participate as observer or contribute to the decision making, dependent on the projected cost per patient treatment or cost per patient per annum for continuing treatment, as follows:

(a) < £25,000

An invitation will be extended to the Medical Director of the relevant Board (or their nominee) to attend as an observer of the process (see section 11 below for definition of terms). The home Board Medical Director or a nominated deputy will be notified before the process begins and the panel's decision will be conveyed to him/her before it is conveyed to the appellant, the Associate Medical Director and the patient.

(b) ≥ £25,000

An invitation will be extended to the Medical Director of the relevant 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 individual case, the Home Board has the opportunity of providing feedback to inform the process for future Exceptional Case Appeal Panels.

## 5. Timescale

The appeal will be heard, within 20 working days of submission. A balance should be struck to allow collation and review of the necessary evidence, while avoiding delay in outcome. It is recognised that some circumstances will demand the Panel to be convened urgently. This will be considered on a case by case basis, with guidance from Specialist Advisers, as required.

## 6. Nature of evidence

The initial onus is on the appellant. Typically this will include:

- The original IPTR documentation which should include a clear description of how the appellant considers the patient meets the referral criteria for an Individual Patient Treatment Request.
- The incorporation of peer review into the evidence base, e.g. an MDT report or the opinion of the Clinical Team Lead if applicable
- The patient statement from the original IPTR documentation, if completed.
- A completed IPTR Appeal Form which should provide a clear description of which part(s) of the IPTR process the appellant considers that the IPTR panel did not implement appropriately, either in terms of the process or the interpretation of evidence

The original IPTR documentation including the IPTR panel rationale should be made available, along with the supporting review of the evidence base produced by the relevant Lead Clinical Pharmacist or by Medicines Information which provides a collation of the following:

- National prescribing advice e.g. SMC/ NICE / SIGN
- Assessment report / referral advice from an external specialist (if applicable)
- Interpretation/overview of the evidence base

This evidence will be submitted to the PMG Secretariat (or nominee) who will confirm that the requirements are complete and will arrange circulation to the Panel Members. In each case, the patient and / or his / her representative will be informed of the process. Only in exceptional circumstances and at the discretion of the Chair, will evidence be permitted for inclusion outwith the normal arrangements for pre-circulation.

## 7. Review of Evidence

The Panel (section 3) will be chaired by the Board's Medical Director. In addition to the Panel Members and PMG Secretariat (as above), the evidence will be heard by:

- the appellant(s)
- the Chief of Medicine (CoM) or nominee of the Directorate
- the Clinical Director (CD) of the therapeutic speciality
- a Specialist Adviser(s), at the discretion of the Chair

Completion of 'declaration of interests' will be confirmed for all participants at the outset.

Firstly, the case in favour of the appeal will be presented by the appellant(s). This information will then be open to questions from all participants. Secondly, the basis for rejection of the initial IPTR will be presented by the Chief of Medicine and will be open to questions from all participants. Thirdly any other competent business will be reviewed.

At the conclusion of the proceedings, the Chair will confirm that all the participants had a fair hearing.

## 8. Panel decision

In private session, the Panel including (where relevant) the Expert Adviser, will consider whether the IPTR process has been correctly applied by the original IPTR panel and whether the original decision can be justified in light of the evidence submitted, taking into consideration the submitted evidence from both sides. The Home Board Representative will also be in attendance, as will the PMG Secretariat to record proceedings. When this discussion is complete, the Expert Adviser(s) will retire to leave the Panel to reach its verdict.

The onus of responsibility rests with the appellant to demonstrate that the following criteria are satisfied in line with CMO(2011)3:

- 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.

The Panel will make their decision, typically on the same day of the appeal. Each panel member is entitled to vote for or against the appeal (or to abstain). Should the vote be evenly split, then the Panel Chair has the right to a casting vote.

The Panel's decision will be final and will lead to one of the following outcomes:

(a) If the appeal is upheld on the basis of a flaw in the original IPTR process, then the Appeal Panel can proceed to reconsider the evidence
(b) If the appeal is upheld on the basis of reconsideration of the evidence, the appellant is eligible to prescribe the medicine on the NHS with immediate effect
(c) If the appeal is declined, the position of the Directorate, in response to the original IPTR application, will stand; the medicine cannot be prescribed on the NHS

## 9. Communication of decision

The appellant will then be informed by the Chairman and the Secretariat of the decision and the rationale for it. The appellant will be responsible for advising the patient and/or his/ her representatives. On reaching a decision, a written note of the outcome should be provided to the requesting clinician, by the Appeal Panel Chair. This will provide a brief summary of the rationale for the decision will set out the options available to the patient.

The Directorate representatives will be informed immediately afterwards, to include review of any immediate actions required.

The priorities for communication of the outcome are:

- Appellant and any associated clinical personnel caring for the patient
- Patient / carer / patient representative / family members (via the appellant)
- COM / CD / Service Manager / Lead Clinical Pharmacist
- Lead Pharmacist, Medicines Policy and Guidance
- Board Chief Executive / Director of Finance
- Scottish Medicines Consortium Chair (or deputy), where relevant
- Press Office

## 10. Completion of report

The PMG Secretariat should draft a full report, for the attention of the panel members within 5 working days of the Panel Hearing. This will record the detail of the proceedings, the evidence presented, the issues highlighted and the rationale for the decision. An Executive Summary will also be prepared as the basis for communication to a wider audience. Both reports will be approved as an accurate record by:

- the panel members
- the specialist adviser(s)
- the appellant(s)
- the Directorate representatives
- the patient representative

The target timescale for completion of this consultation exercise across all the participants is 20 working days. The patient and/or his/her representative will also be given an opportunity to comment. Any further actions will be followed up through the Directorate's medicines advisory structures.

## 11. Definition of terms

"Home Board":
A Health Board outwith NHS GG&C which has requested NHS GG&C involvement in a patient's case.

"Clinical Responsibility":
A home Board may refer a patient to a NHS GG&C clinician for either advice or treatment or both.

1. Where advice alone is requested, the home board clinician retains responsibility for the patient's treatment including the choice of medicines to be prescribed. In such instances, the Formulary processes within the home Board apply.
2. Where an NHS GG&C clinician is requested to assume clinical responsibility and undertake treatment, the NHS GG&C Formulary processes apply. This is the case in whichever setting or location the NHS GG&C clinician is providing the service, including outpatient clinics within the geographical boundary of the home Board. Application for use of a non-formulary medicine relates to the NHS GG&C Formulary and IPTR processes.
3. Where treatment is shared e.g. with a surgical patient requiring chemotherapy, the relevant process will align with the person taking responsibility for the prescribing.

"Observer":
This nominee has observing rights only with no participation or voting rights. The person observes the whole process including the private session(s). This ensures that the process is consistent for all patients, regardless of whether they are patients of NHS GG&C or a home Board. It also ensures that the process is subject to external review. The Observer provides communication back to the home Board, both on the immediate decision and, if required, to inform feedback on process improvements to NHS GG&C.