5.2 (SUPPLEMENT): INTERIM POLICY STATEMENT: INDIVIDUAL PATIENT TREATMENT REQUESTS (IPTRS) AND PEER APPROVED CLINICAL SYSTEMS (PACS)

IMPORTANT NOTE: This interim policy statement is a supplement to and should always be read in conjunction with 5.2 Policy for the Management of Individual Patients Treatment Requests.

PURPOSE OF PAPER

This statement is to provide clinicians with guidance on the management of IPTRs in the transition phase before PACS are implemented. This policy statement should be read in conjunction with 5.2 Management of Individual Patient Treatment Requests.

NATIONAL CONTEXT

- SG New Medicines Review: Response to the Health & Sport Committee, October 2013
- "Access to Medicines – Transitional arrangements for processing individual patient treatment requests", SGHD/CMO(2013)20, 5 November 2013
- "Proposed approach to deal with the transitional period from IPTR to PACS", CMO / CPO letter, 11 December 2013

LOCAL CONTEXT

- NHS GGC Medicines Policy 5.2: "Management of Individual Patient Treatment Requests"
- NHS GGC Medicines Policy 5.3: "IPTR Appeal Process"
- "Access to new medicines: Transitional arrangements for processing IPTRs", Letter to CMO / CPO from the WoS and Lothian NHS Boards' Medical Directors and Directors of Pharmacy, 19 November '13

POLICY STATEMENT

Overall consolidation

- clinicians making a request should have all the relevant information
- patients should be given the GGC IPTR Patient Information Leaflet, including reference to internal and external sources of support and advice
- the process for decision making remains unchanged; the onus remains on the specialist to demonstrate alignment of the case with existing IPTR approval criteria
- these are clinical criteria which are assessed on a case by case basis; current GGC policy makes no reference to 'exceptionality'
- decisions are not influenced by consideration of cost effectiveness or affordability
- this approach applies to all GGC patients and patients with WoS postcodes who are under the care of a GGC physician
- the option remains for the specialist to appeal against the original directorate IPTR decision; this appeal will be heard by a Board panel, as before.

Changes at Directorate level (IPTRs)

- the Directorate panels will exercise '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 expectation that panel membership should include a clinical specialist
  - the option for the IPTR / PACS applicant to contribute directly to the panel discussion
  - the additional emphasis on 'peer approval' where the evidence is equivocal, where the panel opinion is split or where reasonable doubt exists for rejection of the IPTR criteria

Changes at Board level (IPTR appeals)

- the appeal panel will exercise additional 'flexibility' in cases where the decision is in the balance or where further clinical opinion is considered desirable, by deferring to designated clinical specialists from other boards for a second opinion on specific questions. This will be influential in the final outcome.

RATIONALE

- The aim is that patients should be positively supported and should not be adversely affected during the transition from IPTR to PACS, with patients / specialists and IPTR panel members kept fully informed
- NHS GGC policy statement now supports a balance of existing and new arrangements for all individual requests for licensed medicines in their licensed indications which are not recommended by SMC
- The CMO / CPO letters refer to "the decision making criteria in the extant best practice guidance" and IPTR panels should exercise "flexibility in their decision making"
- NHS GGC acknowledges the principles of PACS are to increase patient access to new medicines, by promoting greater clinical involvement in decision making about individual cases.
- NHS GGC will therefore introduce policy variations, as above, in the spirit of the New Medicines Review and subsequent CMO / CPO correspondence (national context above)
- This policy is a form of 'peer approved clinical system' with retention of the existing basis for decision making until an acceptable alternative is agreed which is consistent and equitable, locally and nationally
- It will be subject to review on 1ST July 2015, or earlier in response to further guidance from SGHD.