NHS Lanarkshire Protocol for Peer Approved Clinical System Tier 2 Requests (PACS 2)

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Governance or Assurance Committee	**Area D&T Committee**
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CONSULTATION AND DISTRIBUTION RECORD	
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CHANGE RECORD

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INTRODUCTION

The NHS Scotland Directors of Pharmacy commissioned a short life working group to prepare guidance for Health Boards in order to promote consistency of application of the Peer Approved Clinical System Tier 2 (PACS 2) across NHS Scotland. This local guidance has been prepared to reflect this national work and Scottish Government guidance noted in Guidance on the Implementation of the Peer Approved Clinical System (PACS) Tier Two issued 29 March 2018.

1. GENERAL STATEMENT

1.1. SMC advice for a particular medicine and indication is made on the basis of an evaluation of the comparative clinical evidence and cost effectiveness compared with standard clinical practice in Scotland. The PACS 2 process is not intended to overturn the SMC advice, but provides an opportunity for senior clinicians, on a case-by-case basis for individual patients, to request use of a licensed medicine as outlined below. The PACS 2 process takes into consideration the application of set decision making criteria and the wider benefit of the request to the NHS (see section 7).

2. APPLICABILITY AND SUBMISSION

2.1. The PACS 2 process is applicable to requests for access to a licensed indication where:

- The SMC has considered a submission for a medicine and has issued 'not recommended' advice;

or

- The request relates to use of the medicine out-with a SMC restriction;

or

- Where a medicine has been submitted but the SMC has yet to issue advice on the medicine where the clinician responsible believes a delay in treatment until publication of SMC advice would result in a significant adverse outcome for the patient.

2.2. The PACS 2 process is open to senior clinicians who are directly responsible for a patient's care. This may be a Consultant, GP or Lead Non-Medical Prescriber in a specialist area.

2.3. It is the responsibility of the clinician to make the case for prescribing the medicine using the PACS 2 request form.

2.4. There is a national standard electronic form for PACS 2 applications. This is an electronic form which should be completed, saved and submitted electronically.

2.5. The requesting clinician should brief the patient (or their representative) on treatment options and likely benefits, associated risks, monitoring of outcomes, review of benefit and criteria for discontinuation.

3. PEER SUPPORT

3.1. The requesting clinician must seek peer support for their application from another clinician. Peer Support should be completed by another clinician with experience in treating the condition for which the medicine is being requested. Part C of the PACS 2 request form should be completed independently by the designated reviewing clinician.

3.2. In providing a peer review of the information presented for the patient, the reviewing clinician is stating that:

- any alternative SMC accepted medicines have been considered and excluded as suitable treatment options

and

- the patient characteristics detailed and the clinical evidence presented demonstrate the potential that the patient will achieve a measurable clinical benefit at least comparable to if not better than that experienced by the population considered by SMC.

3.3. The reviewing clinician may be from within the health board where the request is being made. If there are no other appropriate clinicians locally, then experts within the NHS from elsewhere in Scotland or the UK can provide the peer review statement.

3.4. Where the care of the patient in question is under the care of a multi-disciplinary team, clinicians should seek their support for the PACS 2 application and indicate this in Part A of the request form. Please note Part C: PEER REVIEW section of the form still requires to be completed

4. NATURE OF EVIDENCE

4.1. The Board's PACS 2 Panel will consider the information submitted by the clinician on the PACS 2 request form. Evidence and information from clinicians to demonstrate the fulfilment of the decision making criteria and that prescribing the medicine is of benefit to the patient and to the NHS may include:

- SMC advice (where available)
- Any new evidence that has emerged since an SMC decision
- Peer reviewed evidence, e.g. a medicines summary information
- Expert opinion
- Rationale for why alternative SMC accepted medicines are unsuitable, for example, intolerable side effects, contraindications or other treatments being ineffective
- The balance between benefit and risk (for example side effects or contraindications)
- Individual characteristics which have been shown to have a positive influence on response e.g. specific genetic sub-types where clinical evidence is stronger
- Other UK guidance or formal health technology assessment with new evidence that has emerged since The SMC advice was published which is of relevance to the individual patient
- Impact of the requested treatment on healthcare, e.g. cost effectiveness and the balance of benefit and risk in the context of what is the wider benefit to the NHS

5. PACS 2 PANEL MEMBERSHIP

5.1. The Panel for reviewing a request via PACS 2 will be clinically composed and will typically include:

- Senior physician (e.g. Divisional Medical Director, Clinical Director, Medical Director) or nominated deputy
- Senior pharmacist
- Other relevant healthcare professionals as appropriate

5.2. 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

6. PROCESS FOR NHS LANARKSHIRE PATIENTS REFERRED TO ANOTHER BOARD

6.1 NHS Lanarkshire may request the involvement of another board in a patient's care; that request can be for advice, or treatment, or both. It has been agreed via the West of Scotland Regional Planning Group that when a patient has been referred by their home board to another (host) board the relevant processes align with the person taking responsibility for the prescribing and the following principles apply:-

- Where the referral is for advice alone, then the patient's home board retains responsibility for the patient's treatment, i.e. the patient's home board will convene the PACS 2 Panel.
- Where the referral to another (host) board is for that board to undertake treatment then the processes of that host board apply – including their PACS 2 process should their clinician seek to request a non-approved medicine.

  This is the case in whichever care setting or location the host board clinician is providing the service, including outpatient clinics within the geographical boundary of the home board, e.g. an oncologist from the Beatson Oncology Centre providing clinics within an NHS Lanarkshire site.

6.2 The patient's home board has the right to full membership of the host board's PACS 2 Panel when the medicine cost threshold of £25,000 per patient per annum is exceeded.

7. PANEL CONSIDERATIONS FOR DECISION MAKING

7.1. The Panel will initially consider whether the request has clearly demonstrated that the patient's individual clinical circumstances meet the following decision making criteria:

i. The clinician has demonstrated that a reasonable attempt, or appropriate consideration, has been made to treat the patient in the first instance with medicines currently accepted by the SMC for routine use in NHS Scotland for this condition and for the patient in question that these medicines are deemed unsuitable or have been found to be ineffective;

AND

ii. The clinician has presented an evidence-based case to demonstrate the potential that the patient will achieve a measurable clinical benefit at least comparable to if not better than that experienced by the population considered by SMC.

7.2. The Panel will, in addition, consider the wider benefit of the request to the NHS. Evidence and decision making should focus on the clinical merit of the application for the individual patient. Consideration should be given to the wider benefit to the NHS, the Panel may consider aspects such as the level of health gain in the context of NHS resource consumed and the balance of benefit and risk.

7.3. The Panel should also consider whether availability elsewhere in the UK is driven by new evidence that has emerged since an SMC decision was published which is of relevance to the individual patient.

7.4. If the Panel agree the decision making criteria have been met and that prescribing the medicine is considered of benefit to both the patient and the NHS then the request should be supported. If the Panel feels the decision making criteria have not been met and/or the medicine is not considered of benefit to the patient and the NHS then the request should not be supported.

7.5. Appendix 1 provides Panels with a decision checklist tool to assist in the consideration of request and to help promote consistency in approach.

8. TIMESCALE FOR DECISION

8.1. 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 the Panel Chair. The clinician will be responsible for outlining any time dependent factors.

9. DOCUMENTATION AND COMMUNICATION OF DECISION

9.1. The decision of the Panel will be recorded in full by the chair of the Panel in the part D of the PACS 2 request form. The rationale for the decision should be as helpful and comprehensive as possible. The rationale should specifically relate to the decision making criteria for acceptance and the wider benefit to the NHS.

9.2. A completed decision checklist (appendix 1) should form the basis of the content recorded in the Main discussion points of Panel section in the Part D of the PACS 2 request form

9.3. The chair of the Panel will then inform the requesting clinician of the decision in writing or via email by providing a copy of the fully completed PACS 2 request form including the decision and rationale within 5 working days, or within the same day for cases deemed to be an emergency.

9.4. In some cases, follow-up discussions between the chair of the PACS 2 Panel and the requesting clinician may be helpful to clarify the discussion.

9.5. The decision should be communicated to the patient/patient representative by the clinician responsible for their care within one working day and there should also be discussion with the patient around the decision, future treatment options and consideration of application to the National Review Panel if relevant.

9.6. It is good practice to file a copy of the completed PACS 2 request form in the patient's medical notes.

9.7. Where the patient is not satisfied with the way the PACS 2 request was handled, this could include progressing their concerns via the NHS complaints process. Complaints and national reviews about the PACS 2 process can be progressed simultaneously and will not impact on each other.

9.8. Once clinical agreement has been reached by the Panel the financial consequences of this decision needs to be sent to the appropriate management team so that this can be accounted for within financial planning and budgetary processes.

10. REQUEST FOR REVIEW OF DECISION

10.1. In the event where a requesting clinician and patient feel they have grounds for a review of the local decision, the clinician (on behalf of then patient) is able to ask for the decision to be referred to the National Review Panel. Referral for a review of the decision can only be made by the clinician responsible for the patient's care.

10.2. The requesting clinician is required to complete Appendix 1 of the original submission form. Full information on the process and access to the review form is available on the Healthcare Improvement Scotland website.

Please note that paperwork that is incomplete or has been completed incorrectly will be returned to the requesting clinician and will not be considered by the National Review Panel

10.3. The National Review Panel will independently review the original information and will either make a finding:

- that a decision, with reference to the information and/or evidence on which that decision is based, is or is not reasonable, or
- on whether or not due process has or hasn't been followed

10.4. The National Review Panel will meet on a monthly basis. However, ad hoc meetings of the National Review Panel will be convened when the clinical urgency of the case dictates that this is necessary. Review panel dates and submission dates will be available on the Healthcare Improvement Scotland website (www.healthcareimprovementscotland.org).

10.5. The National Review Panel will issue its findings and recommendations to the Board Chief Executive, Medical Director and Director of Pharmacy, ideally within one day of the panel meeting.

10.6. The NHS Board Medical Director must inform the requesting clinician as soon as practicable, taking into consideration any clinical urgency, of the National Review Panel's decision and recommendations.

10.7. The final decision is for the NHS Board to determine and so the NHS Board will convene a new PACS 2 panel to consider the request and ensure that the final PACS 2 decision is communicated within a timescale that takes into account any associated clinical urgency and/or the patient's clinical needs.

10.8. It is the responsibility of the requesting clinician to inform the patient or the final decision. There will be no further right of appeal

11. SUPPORT FOR THE PATIENT

11.1. The patient is supported and guided through the PACS 2 process primarily by his/her clinician, who will outline the terms on which a PACS 2 request can be submitted and the basis of the case in addition to answering any specific questions the patient may have.

11.2. Each patient should be given a patient information leaflet which will provide information relating to the PACS 2 process including an overview of the process, sources for further advice, timescales and the reviews process.

12.DECLARATION OF INTERESTS

12.1. Relevant declarations of interest of all persons involved in the process should be captured using the PACS 2 request form.