Peer Approved Clinical System Tier 2 (PACS2)

Purpose of this procedure:

This procedure is to support the policy issued by the Scottish Government on the implementation of Peer Approved Clinical System (PACS) Tier 2.

The Procedure:

1.0 Introduction

The Chief Medical Officer and the Chief Pharmaceutical Officer wrote to boards on 29 March 2018 [Appendix 1] to provide guidance on the implementation of the Peer Approved Clinical System (PACS) Tier Two, also known as PACS2, which replaces some of the processes previously covered by the Individual Patient Treatment Request (IPTR) policy.

There is a main Patient Treatment Request (PTR) panel and a separate cancer medicines management committee (for adult patients). The main PTR panel will have three parts to its meetings: PACS1 applications, PACS2 applications and other PTR applications.

All PACS1 and PACS2 application are to come to the main panel.
Other PTR applications for cancer medicines in adult patients can go to the cancer medicines management committee, PTR requests from other specialities should be submitted to the main panel.

The NHS Lothian PTR Panel is also responsible for oversight of the following NHS Lothian procedures:

Peer Approved Clinical System (PACS) Tier One, also known as PACS1
For 'ultra-orphan' medicines not recommended for use by SMC.
Procedures for SMC Non Submissions
To be further defined. In the interim, refer to IPTR policy
Procedures for Surgical Procedures Not Recommended by NHS Policy
To be further defined. In the interim, refer to IPTR policy

1.1 Aim of the Policy

The aim of the Scottish Government policy is to enhance the consistency of approach across all NHS Boards when considering medicines that have not been accepted for routine use in NHS Scotland.

A patient treatment request can only be sought where the clinician fully supports the request. The clinician is defined as the hospital consultant or General Practitioner with overall clinical responsibility for the patient.

Decisions on medicines, including those not recommended by the SMC and therefore not routinely available in NHS Lothian, are published on the Lothian Joint Formulary website at http://www.formulary.nhs.scot/east/formulary-decisions/

1.2 Procedure Objectives

This procedure and its supporting appendices will address the following items:

- Circumstances under which PACS2 will be considered
- Referral Criteria
- Generic core composition of the PTR panel
- Evidence
- Timescales for decisions
- Appeals

1.3 Scope

There are no clinicians (including non-medical prescribers) exempt from this policy when a medicine meeting the appropriate criteria for PACS2 is considered for use in a patient.

This policy is applicable to patients being treated within primary care and secondary care across NHS Lothian. The process will apply to **new** patients. Submissions to the PTR Panel will not be required for patients who have already been initiated on a medicine through the NHS, although there is an opportunity to monitor and review patients.

PACS2 process is designed to provide an opportunity on a case by case basis to request the use of a licensed medicine that

- is a medicine for an indication that has been considered and not recommended for use in NHS Scotland by the Scottish Medicines Consortium (SMC); or
- is a medicine accepted for restricted use by the SMC, but the intended use is out with SMC restrictions; or
- is a medicine which has been submitted to and is awaiting/undergoing evaluation by the SMC.

2.0 Philosophy, Principles and Objectives

Scottish Government guidance seeks to ensure a consistency of approach in relation to the introduction and availability of newly licensed medicines across NHS Scotland. This is to ensure that all patients across NHS Scotland, regardless of health board, have equal access or opportunity to be considered for treatment with a medicine even if not recommended by the SMC.

The paperwork is included as Appendix 2
Policy statements are included as Appendix 3
Decision checklist included as Appendix 4
Non-approved medicines process flowchart is included as Appendix 5
Patient Information Leaflet is included as Appendix 6

3.0 Roles and Responsibilities

3.1 Patients, Relatives and Carers

Information for patients and the public (Appendix 6) has been developed by the Area Drug and Therapeutics (ADTC) Collaborative, hosted by Healthcare Improvement Scotland. The ADTC Collaborative team worked with healthcare professionals, public partners, public involvement groups and patient and carer support groups across NHS Scotland to develop the medicines factsheet.

The clinician will explain the application process and the appeal process to the patient. The responsibility of the patient is to ask if they do not understand what they are being told.

Relatives and carers are integral to supporting their family member. The clinician will explain the application process and the appeal process to relatives and/or carers.

3.2 NHS Lothian Staff

3.2.2 Clinicians

Clinicians' (both the clinician applying for their patient as well as the clinician providing peer support) responsibilities are included in Appendix 3, National PACS2 policy statements.

Applying clinicians should include any service implications that may arise as a result of this treatment being approved under the 'any additional information' section of the PACS 2 form.

Applying clinicians should liaise with pharmacy to gain support for the application when relevant (see below), and to ensure that the pharmacy implications of the medicine being approved for use can be taken into consideration.

3.2.3 Clinical Directors and Associate Medical Directors (secondary care only)

There is no formal requirement for the CD and the AMD, to sign-off the application. It would be considered best practice for all applications to be discussed with the management team prior to the application being made.

3.2.4 Clinical Management Team (CMT) Director of Operations or HSCP Clinical Director

There is no formal requirement for the Director of Operation or HSCP Clinical Director, to sign-off the application. It would be considered best practice for all applications to be discussed with the management team prior to the application being made.

3.2.5 Hospital Clinical Pharmacist or Primary Care Pharmacist

Hospital Clinical Pharmacists or Primary Care Pharmacists will be responsible for advising their respective clinicians on any PACS2 application. These duties might include:

- Check the medicine and indication for treatment being considered and the patient's circumstances and advise on whether it should be a PACS1, PACS2 or PTR request (refer to flow chart in Appendix 5).
- Support the clinician in preparing the evidenced-based case for the individual patient. Guidance on the nature of evidence to be presented is included in section 4 of Appendix 3.
- Consider the requirements for the introduction of a new medicine, this might include: timely ordering and supply of the medicine, protocol development, aseptic worksheets, team education.
- Consider the service implications for delivery of the medicine

3.2.6 Medicines Information

The Lothian Medicines Information Service (LMIS) has access to other evidence briefing templates prepared across Scotland via the Association of Scottish Medicines Information Pharmacists. LMIS will be responsible for checking if a prior evidence briefing template meeting the medicine/indication being considered has been prepared. If available an electronic copy will be supplied. This may be useful in completing the application form.

3.2.7 NHS Lothian PTR Administrator

The PTR Administrator will be responsible for the receipt and logging of requests and appeals.
The PTR Administrator will capture all relevant information from the Panel discussion on the decision record (Appendix 2) and the panel decision checklist (Appendix 4.)
Feedback to the clinician will be provided (Appendix 2) by the PTR Administrator within 5 working days of the Panel meeting. NHS Boards are asked to maintain accurate and up to date information on decisions, appeals and their outcomes in order that information can be provided on request.
The PTR Administrator will perform these duties. In addition, the PTR Administrator will be responsible for providing hospital/community pharmacies with information on individuals approved to receive a medicine via PTR approval on an ad hoc basis if required prior to medicine being dispensed.

3.2.8 NHS Lothian PACS2 Panel

The panel is responsible for ensuring that the governance processes are transparent and can withstand scrutiny.

The Panel will consider the national guidance for PACS2 guidance (Appendix 3) when making its decisions. Panel members should refer to the decision making grid when discussing PACS2 applications (Appendix 4). This grid will also inform the panel meeting note and the decision record.

The membership of the PTR panel may include:

Medical Director (Chair) [or nominated deputy]
Chair of Cancer Medicines Management Committee [or nominated deputy]
Director of Pharmacy [or nominated deputy]
Nurse Director [or senior nurse deputising]
Chief Operating Officer [or nominated deputy]
HSCP General Manager or Chief Officer [or nominated deputy]
Director of Strategic Planning [or nominated deputy]
General Practitioner

Chair of Formulary Committee [or nominated deputy]
Public Health representative
Finance representative
Medical Director, Acute Services
Medicines Management Pharmacist
Associate Medical Director, Primary Care [or nominated deputy]

Co-opted members can be present as required (e.g. independent clinical specialist and/or pharmacist specialist for indication for treatment; primary care pharmacist).
The NHS Lothian PTR Panel will meet monthly unless an emergency case arises. Where an urgent decision is required, the Medical Director would be the point of contact. The Medical Director will assume responsibility for approval; and may use telephone or an e-mail of relevant PTR Panel members to reach decision.

The final decision of the PTR Panel will be communicated to requesting clinician within five working days of the meeting. It will be the clinician's responsibility to communicate to the patient within one working day of receiving reply.

4.0 Appeals

The National Review Panel is a function within Healthcare Improvement Scotland (HIS) who will facilitate support to the Panel. HIS will be responsible for its governance and will provide all the necessary support to the Panel. HIS personnel will not be part of the review process.

In the event where a requesting clinician and patient feel they have grounds for a review of a local PACS Tier Two decision, a National Review Panel will be established to independently review and make recommendations to the relevant NHS Board on their original decision. This replaces each NHS Board's own local appeal process.

HIS will ensure that the National Review Panel will be clinician-led and include appropriate senior medical and pharmacist perspectives. The individuals involved in the Panel should be fully conversant with the National Review Panel policies. HIS will give due consideration to any training required for Panel members.
The review process will accommodate reviews on either of the following grounds:

- the NHS Board has failed to follow due process and the situation cannot be resolved locally; and/or
- the NHS Board has reached a decision which could be deemed unreasonable in light of the evidence submitted.

See Appendix 1 Annex B for further information.

Associated materials/references:

Appendices

Appendix 1	Scottish Government letter and guidance

Appendix 2	Scottish Government template application form
Appendix 3	National NHS Board policy statements
Appendix 4	Panel decision checklist
Appendix 5	Non-approved medicine process flowchart
Appendix 6	Patient Information Leaflet