Directorate for Chief Medical Officer
Chief Medical Officer
Chief Pharmaceutical Officer

The Scottish Government

Dear Colleague

GUIDANCE ON THE IMPLEMENTATION OF THE PEER APPROVED CLINICAL SYSTEM (PACS) TIER TWO

Introduction

I am writing to inform you about the implementation of PACS Tier Two to replace your current Individual Patient Treatment Request (IPTR) processes.

Purpose

The key purpose of this guidance is to provide a revised framework to support NHS Boards in the development of local policies to enhance the consistency of approach across all NHS Boards when considering medicines that have not been accepted for routine use in NHSScotland.

Overview

PACS Tier Two introduces refreshed decision making criteria, clearer accompanying guidance and the establishment of a National Review Panel to enhance consistency in decision making processes across the country. It also retains key elements of the original IPTR process.

The PACS Tier Two process is designed to provide an opportunity for clinicians, on a "case by case" basis for individual patients, to request the use of a licensed medicine (other than an ultra-orphan 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 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.

Access to ultra-orphan medicines, unlicensed medicines, use for indications outside of the marketing authorisation (off-label) and medicines which are non-submissions or have not yet been submitted to SMC are not covered by PACS Tier Two.

29 March 2018

Addresses

For action
Chief Executives, NHS Boards
Medical Directors, NHS Boards
Directors of Pharmacy, NHS Boards
Directors of Finance, NHS Boards

For information
Chairs, NHS Boards
Directors of Public Health, NHS Boards
Chair, Scottish Medicines Consortium
Chief Executive, Healthcare Improvement Scotland
Area Clinical Forum Chairs

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Applications to access ultra-orphan medicines not recommended by SMC should continue to be considered using the PACS Tier One process. This is currently being piloted nationally and will be reviewed in due course.

We are also progressing work on the Review of Access to New Medicines recommendation in relation to the Scottish Model of Value.

Guidance

Attached to this letter is guidance and PACS Tier Two paperwork which seeks to set out the key components of the process that NHS Boards should, as a matter of good practice, seek to apply in accordance with local circumstances.

The Area Drug and Therapeutics Committee (ADTC) Collaborative will ensure the ongoing review and development of the PACS Tier Two paperwork and provide relevant best practice statements as appropriate. This includes ensuring that there is a consistent process across all NHS Boards to consider medicines which are non-submissions or have not yet been submitted to SMC.

A six and twelve month review, which will take account of the impact of the guidance including the National Review Panel, will be undertaken in partnership with NHS Boards. There will also be an ongoing scrutiny component established to support the implementation in order to ensure that enhanced consistency of approach is achieved.

This guidance replaces all previous guidance on IPTRs as the PACS Tier Two process will replace the IPTR process.

Actions for NHS Boards

Decisions regarding the provision of NHS Services remain matters for NHS Boards; and clinicians remain responsible for clinical decisions regarding the care of individual patients.

NHS Boards are asked to ensure their local policies are aligned to this guidance from **1 June 2018** subject to local governance processes.

NHS Boards are further asked to confirm, by **Friday 18th May 2018**, that they have robust systems in place to collate core data, as set out in Annex A, in relation to PACS Tier Two, including the requirement to be able to produce high level management "in confidence" information for the Scottish Government on request.

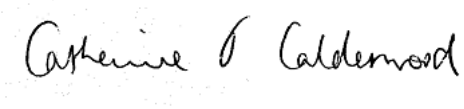
The guidance comprises three annexes**:**

- **Annex A** sets out the specific guidance for PACS Tier Two applications

- **Annex B** sets out the specific guidance on the operation of the National Review Panel

- **Annex C** sets out the new PACS Tier Two paperwork to be used for all applications.

Yours sincerely



Dr Catherine Calderwood
Chief Medical Officer

Dr Rose Marie Parr
Chief Pharmaceutical Officer

ANNEX A

Guidance for PACS Tier Two Applications

PACS Tier Two Process

The PACS Tier Two process provides an opportunity for clinicians, on a "case by case" basis for individual patients, to request the use of a licensed medicine (other than an ultra-orphan 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 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.

Access to ultra-orphan medicines, unlicensed medicines, use for indications outside of the marketing authorisation (off-label) and medicines which are non-submissions or have not yet been submitted to SMC are not covered by PACS Tier Two.

Applications to access ultra-orphan medicines not recommended by SMC should continue to be considered using the PACS Tier One process. The ADTC Collaborative will work with NHS Boards to ensure that there is a consistent process to address requests for use of a medicine which has either been a non-submission or has still to be submitted to SMC.

Standardised PACS Tier Two paperwork has been developed and must be used by all NHS Boards. Please see Annex C for further detail.

Decision Making Criteria for PACS Tier Two Requests

The responsibility for making a request through the PACS Tier Two process rests with the clinician who wishes to prescribe the requested medicine. The requesting clinician is required to demonstrate the clinical case for the patient to be prescribed the medicine within its licensed indication(s) where the following criteria apply:

(i) The clinician can demonstrate 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 can present 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.

PACS Tier Two Decisions

PACS Tier Two decisions are clinical decisions. As was the case with the previous IPTR process, the cost of the medicine must not be part of the decision making process.

A PACS Tier Two Panel will consider the clinician's request for use of the medicine and whether the evidence and information presented by the requesting clinician and the peer review statement supports the case that the individual patient is likely to achieve measurable clinical benefit that is at least comparable to if not exceeding that which is normally expected of that medicine compared to the population considered by SMC in its assessment. The Panel will also consider the wider benefit to the NHS.

If the PACS Tier Two Panel agrees 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 approved.

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 approved and the clinician should be informed of the rationale for this decision, for onward communication to the patient.

PACS Tier Two Evidence and Information That Will Be Considered

It is the responsibility of the requesting clinician to provide an evidence-based case detailing all the relevant information on the reasons why their patient would receive measurable clinical benefit from the requested medicine that is at least comparable to if not exceeding that which is normally expected of that medicine compared to the population considered by SMC. This includes explaining why an SMC accepted medicine would not be suitable.

PACS Tier Two decisions should be based on a range of evidence and information including:

(i) SMC advice (unless assessment is in progress);

(ii) any new evidence that has emerged since an SMC decision;

(iii) the decision making criteria; and

(iv) the PACS Tier Two request case report from the requesting clinician which details the evidence base for the request in the standard case report documentation (Parts A-C of the paperwork attached at Annex C) which should be used by all NHS Boards for this purpose.

Appropriate evidence includes published, peer reviewed evidence, new emerging evidence still to be published and expert opinion. Patient factors include examples such as intolerable side effects and specific genetic sub-types where clinical evidence is stronger.

Whilst equity of access across other parts of the UK is not one of the decision making criteria both the requesting clinician and the Panel should 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.

Support for Clinicians in Advance of Making a PACS Tier Two Request

It is the responsibility of the requesting clinician to provide full and appropriate detail in the request using the PACS Tier Two paperwork, and paying particular attention to meeting the decision making criteria.

In order to support this, NHS Boards should put in place appropriate mechanisms for clinicians in advance of making an application to ensure applications are submitted as effectively and efficiently as possible and to manage expectations. This includes advice regarding appropriate evidence and completion of the paperwork.

Making a PACS Tier Two Application – Support from Peers/Multidisciplinary Teams

As part of best practice and in order to strengthen the case being made, the requesting clinician must seek peer review for their application from another NHS clinician with suitable experience in treating the condition for which the medicine is being requested. The reviewing clinician may be from within the same NHS Board, but if there are no other clinicians with suitable expertise locally, then experts within the NHS from elsewhere in Scotland or the UK can provide the peer review.

In providing a peer review of the information presented for the patient, the reviewing clinician is considering that (a) any alternative accepted medicines have been considered and excluded as being unsuitable treatment options and (b) the patient characteristics detailed and the clinical evidence presented imply that the response to treatment will be at least comparable to, if not increased, compared to the population considered by SMC.

Part C of the PACS Tier Two paperwork must be completed by the reviewing clinician.

Similarly, where the patient is under the care of a multi-disciplinary team, clinicians must take the opportunity to discuss and gain the support of the team for the PACS Tier Two application and indicate their support in Part A of the paperwork.

Composition of a PACS Tier Two Panel

In establishing a PACS Tier Two Panel NHS Boards should ensure that the Panel will be clinically composed and include appropriate senior medical and pharmacist perspectives. The individuals involved in the PACS Tier Two Panel should be fully conversant with the NHS Board policies on PACS Tier Two. Boards should give due consideration to any training required for Panel members.

NHS Boards should also ensure that the members of the PACS Tier Two Panel are aware of their responsibilities in relation to declarations of any interests which could potentially impact on their impartiality in decision-making.

Timescales for PACS Tier Two Decisions

NHS Boards should undertake preliminary examination of the request and ensure due consideration is given to the urgency of the request given the patient's clinical condition and manage timescales accordingly. The requesting clinician will be responsible for outlining any time sensitive factors the panel ought to be aware of in their case report documentation.

Information for the Public and Patients about the PACS Tier Two Process

NHS Boards should make available to clinicians and the public information on their PACS Tier Two arrangements in accordance with relevant legislation including Equalities legislation. This includes listing the information in the Board's formal scheme of publications. In doing so, NHS Boards should, as a matter of good practice, ensure that such information is fully accessible in an easy read version and is available in different formats. The content could include:

- clarification around what constitutes a PACS Tier Two request;
- how, when and by whom, a PACS Tier Two request can be initiated;
- details of sources of local advice in relation to the PACS Tier Two process;
- a description of who will consider PACS Tier Two requests;
- clarity on the basis on which PACS Tier Two decisions will be reached, and how, when and by whom supporting evidence/information can be submitted;
- the timescales of decision making for PACS Tier Two requests;
- the timescales and methods for communicating decisions to patients/carers/patient advocates for whom a PACS Tier Two request has been made;
- information about the options open to patients when PACS Tier Two decisions have been reached, including information about the grounds on which a request for a national review can be made, how this is done, and by whom, and where local advice on the national review process can be sought.

When patients are going through the PACS Tier Two process they should be signposted to a named individual appointed by the NHS Board to provide advice and support. NHS Boards may decide, with input from the patient, whether this is the clinician responsible for the patient's care or another named person.

Patient and Public Involvement in PACS Tier Two Requests

In line with previous guidance on IPTRs, NHS Boards should secure patient and public involvement in the development of their PACS Tier Two policies and processes through their patient focus and public involvement arrangements.

Patient Involvement in the PACS Tier Two Process

In addressing patient involvement in the PACS Tier Two process, NHS Boards and requesting clinicians should undertake the following:

- the requesting clinician should provide the patient with the PACS Tier Two national patient information sheet as soon as a decision has been taken to make a request through PACS Tier Two.
- the requesting clinician will present the case to the Panel for the medicine on behalf of the patient (or patient's representative) using the PACS Tier Two paperwork. In doing

so, they will have ensured that the patient understands the application which is being submitted on their behalf and has consented to its submission;

- verbal and written statements by patients must not be submitted to the panel;

- where appropriate, the clinician should provide the contact details of suitably trained personnel within the NHS Board who can provide further advice and support to the patient/patient representative, including any other patient information and support mechanisms available.

Communicating PACS Tier Two Decisions

On reaching a decision, the record of the PACS Tier Two decision must be documented in Part D of the original PACS Tier Two paperwork and should be emailed to the requesting clinician within 5 working days, or if possible on the same day if clinical urgency demands this. The record should include the rationale for the decision, including where possible a detailed breakdown of the panel's assessment of the application against the decision making criteria and should be as comprehensive as possible to aid understanding of the decision.

PACS Tier Two decisions should be communicated to the patient/patient representative by the requesting clinician responsible for their care within a timescale previously agreed with the patient/patient representative.

The requesting clinician should discuss the outcome of the PACS Tier Two request in detail, and clarify the options open to the patient for their future treatment. If felt appropriate, the clinician can make an application for a national review of the PACS Tier Two decision via the National Review Panel (see Annex B for information on the review application process).

In addition to the national review process, if a patient is not satisfied with the way the PACS Tier Two process was handled, they can progress their concerns via the NHS complaints process.

Maintaining Accurate Records

NHS Boards are expected to maintain accurate and up to date information on PACS Tier Two requests and their outcomes. These arrangements should facilitate requests from Scottish Ministers for high level summary information in relation to medicines requested and whether or not these were made available.

Data Capture

NHS Boards are expected to capture and share the following data as retrospective "in confidence" summary management reports in line with General Data Protection Regulation (GDPR) principles with the Scottish Government as part of the PACS Tier Two process on a quarterly basis.

<u>PACS Tier Two NHS Board output</u>

- Medicine, strength and formulation
- Status (orphan, end of life etc. according to SMC classification)
- Indication
- Decision (supported/not supported /deferred for further information)
- Grounds for the decision (not supported/deferral)

PACS Tier Two National Review panel output (NHS Board)

- Medicine, strength and formulation
- Indication
- National Review Panel findings (review required/not required)
- Confirmation of advice implementation, decision and date (if appropriate)

The Scottish Government will share this collated data with all NHS Boards quarterly to allow for comparison.

ANNEX B

Guidance on the Operation of the National Review Panel

PACS Tier Two 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 IPTR appeal process.

Composition of a PACS Tier Two Panel

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.

The Panel will undertake a review of the evidence presented and will consider whether due process had been correctly followed and/or that the decision reached was reasonable on the basis of the evidence presented.

National Review Panels will be convened on a monthly basis. Meetings can be held electronically (by WebEx/video and teleconferencing) to support the rapid turnaround of applications. However, ad-hoc meetings of the National Review Panel will be convened when the clinical urgency of the case dictates that this is necessary.

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.

It is the responsibility of the requesting clinician, with the patient's consent, to submit an application to the National Review Panel by completing Appendix 1 of the original PACS Tier Two paperwork submitted to the Board's PACS Tier Two Panel. The requesting clinician should provide a robust case for the review, including any substantiation of procedural impropriety and/or that the decision could not have been made reasonably on the basis of the evidence presented. In the event that the clinician is requesting a review because the NHS Board failed to follow due process then the clinician should also send the Board's PACS Tier Two process.

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.

As with a PACS Tier Two request, NHS Boards should put in place appropriate mechanisms for clinicians in advance of making a request for a national review to ensure applications are submitted as effectively and efficiently as possible. This includes advice regarding appropriate evidence and completion of the paperwork.

PACS Tier Two Review Applications

An application to the National Review Panel must be made by the requesting clinician, through a secure NHS Scotland email address. The clinician should also redact information relating to patient identifiable information in advance of it being submitted to the National Review Panel (via HIS), in line with data protection requirements. The information which should be redacted should be as follows:

Part A: Request Details

- Patient's CHI No
- Patient postcode

Part B: Case for Prescribing

- Any person identifiable references to the patient

Part C: Peer Support

- Any personal identifiable references to the patient

Part D: PACS Tier 2 Decision record

- Any named references to the patient

HIS will notify the Chief Executive, Medical Director and Director of Pharmacy in the relevant NHS Board that an application for a PACS Tier Two review has been made.

PACS Tier Two Review Requests

A request for a national review will not be accepted solely because the clinician and/or patient do not agree with the views or conclusions reached by the local PACS Tier Two Panel.

Where a review is requested because a clinician and patient consider that the conclusion reached by the local Board's PACS Tier Two Panel was not reasonable on the basis of the evidence presented, it will be for the clinician requesting the national review to provide justification for this in their application. The National Review Panel will review the original NHS Board's PACS Tier Two decision on this basis.

Where a review is requested because the clinician and patient consider that the NHS Board has failed to follow due process then the National Review Panel will only accommodate a review in the event where this cannot be resolved locally.

The National Review Panel will not accept applications where new evidence for the medicine emerges or if the original decision was based on a factual inaccuracy. The requesting clinician should pursue a resubmission through the NHS Board PACS Tier Two process.

PACS Tier Two National Review Panel

No new evidence will be considered by the National Review Panel.
The National Review Panel will refer to the decision making criteria used by the local NHS Board PACS Tier Two Panel which is laid out in this guidance.

Evidence to be submitted at the time of request and that will be considered by the National Review Panel includes:

- the original request submitted to the Board's PACS Tier Two Panel (Parts A-D of the paperwork);
- appendix 1 of the paperwork completed by the requesting clinician making the case for procedural impropriety or that the decision could not have been made reasonably on the basis of the evidence presented;
- any additional note of the meeting or evidence relating to the case by the NHS Board; and
- the NHS Board's PACS Tier Two process and procedures.

Both the NHS Board and the requesting clinician will be invited to attend and present at the National Review Panel.

Outcome of the Review Process

The purpose of the review is to consider the reasonableness of a local PACS Tier Two Panel's decision and/or whether due process has been followed. As regards reasonableness this is in the context of whether the decision in question would be deemed reasonable on the basis of the evidence presented. The review process will therefore establish if the ground(s) for review is/are or is not/are not established.

The National Review Panel 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.

In the event that the Panel make a finding that the review ground(s) is/are not established then the NHS Board will **not be expected** to revisit the original decision.

If the ground(s) of review is/are established then the case will be redirected back to the NHS Board who will be expected to convene a new PACS Tier Two Panel in order to revisit their original decision, taking into account the National Review Panel reasoning as to why it considered either the original decision unreasonable in light of the evidence submitted and/or that due process had not been followed.

The National Review Panel will issue its findings and recommendations, using Appendix 2 of the paperwork at Annex C, to the relevant NHS Board Chief Executive, Medical Director and Director of Pharmacy, ideally within one working day of the panel meeting.

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

Final decision

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

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

ANNEX C

Paperwork to be used for all PACS Tier Two and Review Applications

The PACS Tier Two paperwork replaces all existing NHS Board local paperwork and should be used for PACS Tier Two and National Review applications from the 1 June 2018 subject to local governance processes.

The paperwork comprises a national set of PACS Tier Two forms which aims to enhance the consistency of approach across all NHS Boards in Scotland. The ADTC Collaborative will ensure the ongoing review and development of the PACS Tier Two paperwork and provide any relevant best practice statements as appropriate.

All Boards are required to use the same PACS Tier Two paperwork to ensure consistency of approach.

The PACS Tier Two paperwork should be completed, saved and submitted electronically. Paper copies should not be accepted unless in exceptional circumstances.

Please see separate attachment for forms.