5.3: POLICY FOR THE MANAGEMENT OF REQUESTS FOR MEDICINES VIA PEER APPROVED CLINICAL SYSTEM (PACS) TIER 2

Clinician wishes to use licensed medicine for a licensed indication where the medicine falls into one of the following 3 categories:

1. **The SMC has evaluated and issued 'not recommended' advice for the medicine and indication**
2. **The request relates to use of the medicine out-with SMC restrictions**
3. **The medicine and indication have been submitted but the SMC have yet to issue advice**

For medicines that the SMC has either issued 'not recommended' advice following a non-submission or where no submission has yet been made to the SMC, clinicians should follow the original Individual Patient Treatment Request (IPTR) process. Forms are available on Beacon.

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Has (is) the medicine/indication been (to be) considered by SMC under the Ultra-Orphan process?

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Yes
Follow the PACS Ultra-Orphan process
Contact Susan Roberts - susan.roberts10@nhs.net for info

No
Follow the PACS 2 process below

Unsure of Status or which process to .?
For Primary Care contact Gordon Loughran on 01387 220062 or gordon.loughran@nhs.net
For Secondary Care contact Alison Bell on 01387 246246 Ext 32039 or alisonbell@nhs.net
(Pharmacy may require to link with SMC Secretariat to establish status - hcis.smcsecretariat@nhs.net)

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Requesting clinician completes **Form PACS 2** focusing on evidence to support that the patient's individual clinical circumstances meet the two Decision making Criteria

1. 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
2. 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.

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Completed Form PACS 2 is submitted by email to Mary Watson at marywatson@nhs.net

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PACS 2 Panel is convened by Associate Medical Director Ewan Bell and considers the submitted request within an appropriate timeline considering the urgency of the presenting case

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Panel Decision is communicated to the requesting clinician within 5 working days (via completed form with decision documented in Part D (or same day for emergency requests) and clinician should inform the patient of the outcome within 1 working day of being notified

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Copies of all completed requests (including decision) are emailed to marywatson@nhs.net for collation and reporting to Scottish Government on a quarterly basis.

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Reviews of PACS 2 decisions will be conducted on a national basis. In the event the requesting clinician and patient feel they have grounds for review, the requesting clinician should complete the relevant section of the PACS 2 document, redact patient-identifiable data and email to hcis.nap@nhs.net with a copy of the email sent to marywatson@nhs.net

INTRODUCTION

PURPOSE OF POLICY

This policy outlines the NHS D&G management process for medicines requested via the Peer Approved Clinical System Tier 2 (PACS 2) which replaces the previous Individual Patient Treatment Request (IPTR) process.

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 comparators used in Scottish practice at the time and is applicable to the population covered in the advice. 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 (other than ultra-orphan) that is not recommended by the SMC following their appraisal on clinical and cost-effectiveness, is being used out with SMC restrictions, or has been submitted but not yet evaluated by the SMC.

The policy also includes an overview of the process to request a review of a decision of a PACS 2 request.

This policy has been developed to reflect Scottish Government guidance noted in Guidance on the Implementation of the Peer Approved Clinical System (PACS) Tier Twp [Formal reference and Link].

GENERAL PRINCIPLES

OVERVIEW OF PROCESS

For medicines applicable for PACS 2, the senior clinician responsible for the patient's care will submit a request for an individual patient in writing using Form PACS including an element of peer review. This request will then be considered against defined decision making criteria by a PACS 2 Panel.

The detail of the process is found within this policy document.

APPLICABILITY OF THE PACS 2 PROCESS

The PACS 2 process is intended to be used for requests for access to a licensed medicine and indication where:

i. The SMC has considered a submission for a medicine and has issued 'not recommended' advice; or
ii. The request relates to use of the medicine out-with a SMC restriction; or
iii. Where a medicine has been submitted but the SMC has yet to issue advice on the medicine where the clinician responsible believes there is an urgency about access to the medicine and a delay in treatment pending SMC advice would result in a significant adverse outcome for the patient.

The PACS 2 process is open to senior clinicians within NHS D&G who are directly responsible for a patient's care. This may be defined as a Consultant, GP or Lead Non-medical Prescriber in a specialist area.

Access to ultra-orphan medicines is not covered by the PACS 2 process and should be sought via the PACS Ultra-Orphan process (Link to Policy). Likewise, access to unlicensed medicines and licensed medicines being used for unlicensed indications (off-label use) are covered by the separate Unlicensed Medicines Policy (Link to Policy).

PACS SUBMISSION PROCESS

Where the applicability criteria for PACS 2 outlined above are met, the clinician should make the case for prescribing the medicine, focussing on clear evidence relating to the two decision making criteria which are as follows:

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.

A designated request form (Form PACS 2) should be used by the clinician to make the case for prescribing. **Only the information contained in this form will be used to inform the panel's decision** (and any subsequent review of the decision should that be sought). It should therefore be noted that a lack of relevant detail relating to the patient may result in the panel not having sufficient information to ascertain that the request meets the decision making criteria. The documentation is intended to be completed and transferred electronically.

The requesting clinician should ensure that there is open and honest discussion with the patient (or their carer) about treatment options and likely benefits, together with the associated risks. There should be agreement with the patient around monitoring of outcomes and, in line with best clinical practice, a review of treatment if the medicine is not delivering the anticipated benefit.

NATURE OF EVIDENCE

The PACS 2 Panel will consider the information submitted by the clinician on Form PACS 2 which should clearly present evidence and information to demonstrate that the patient's individual clinical circumstances meet the decision making criteria for acceptance.

Evidence and information from clinicians may include:

- SMC advice (where available)
- Any new evidence that has emerged since an SMC decision
- Peer reviewed evidence
- Expert opinion
- Demonstration of an overriding clinical need
- 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

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

Only evidence and information recorded on the PACS 2 documentation will be considered by the PACS 2 Panel. There will not be the opportunity to provide further detail or clarity once the request has been submitted.

PEER SUPPORT

As part of best practice and in order to strengthen the case being made, 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.
In providing a peer review of the information presented for the patient, the reviewing clinician is considering that:

i. any alternative accepted medicines have been considered and excluded as suitable treatment options and

ii. 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.

The reviewing clinician may be from within NHS D&G, but if there are no other appropriate clinicians locally, experts from elsewhere in NHS Scotland or the UK can provide a supporting statement.

Part C of the Form PACS 2 should be completion by a peer supporting the proposed Treatment.

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 From PACS 2.

PACS 2 PANEL MEMBERSHIP

The Panel for reviewing a request via PACS 2 will be clinician-led and will typically consist of:

- The Associate Medical Director
- Senior pharmacist (Minimum of two)
- General Manager or nominated deputy, GP or Consultant from NHS Dumfries and Galloway.
- Other health board representation (if relevant)

All participants will be required to complete the Declarations of Interest record within Form PACS 2.

In some circumstances it may be appropriate for Panel discussion and decision-making to be conducted remotely without the need to meet, however in all cases relevant interests should be declared and recorded.

The roles of the Panel members will differ in relation to their position:

- The Associate Medical Director or Director of Pharmacy deputy will act as chair and will consider the views of the other Panel members before seeking (typically) a consensual decision or (rarely) a majority decision on the request. Should there be a split decision, then the Associate Medical Director has the casting vote
- The senior pharmacist will facilitate an overview of the clinical evidence presented in the request and ensure alignment with due process. Part E of Form PACS 2 is available specifically for this purpose.
- The General Manager has a role to specifically consider the service issues of the request including consideration for the current and future implications on the budget and service.

DECISION MAKING CRITERIA FOR ACCEPTANCE OF REQUEST

The responsibility for a request through the PACS 2 process rests with the clinician who responsible for the care of the patient and wishes to prescribe the requested medicine. It is the clinician who is expected to demonstrate the clinical case for the patient to be prescribed the medicine within its licensed indication(s) where both the following criteria apply:

iii. 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

iv. 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.

OTHER DECISION-MAKING CONSIDERATIONS

Cost must not be considered as part of the decision making process. Evidence and decision making should focus on the clinical merit of the application for the individual patient.

The patient's individual clinical circumstances and clinical benefit should be compared with SMC approved alternatives or best supportive care. 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 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.

TIMESCALE FOR DECISION

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 those involved in dealing with the request. The clinician will be responsible for outlining any time limiting factors the panel ought to be aware of in their case report documentation.

The aim is for the timescale between the receipt of the PACS 2 request and a decision not to exceed 20 working days for routine requests, within 5 working days for requests marked 'urgent' and within 1 working day for emergency requests.

DOCUMENTATION AND COMMUNICATION OF DECISION

The decision of the PACS 2 Panel will be recorded in full by the chair of the panel in the part D of Form PACS 2. 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. This rationale will be considered should a request for a medicine progress to the National Review Panel process.

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

In some cases, follow-up discussions between the chair of the PACS 2 panel and the requesting clinician may be helpful to further strengthen the information outlined in part D of Form PACS 2.

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 and to be able to clarify the options open to the patient for their future treatment, including consideration of review (see further below).

It is good practice to ensure that a copy of the completed Form PACS 2 including the outcome is included in the patient's medical notes. This may be done by scanning the document into the patient's Clinical Portal profile.

A copy of Form PACS 2 detailing the outcome of the request should be emailed to marywatson@nhs.net at the earliest opportunity for collation and use in routine reporting to Scottish Government.

Guidance on requesting a review of a decision made following a PACS 2 request is covered later in this policy.

Additionally, 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.

SUPPORT FOR THE PATIENT

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.

The patient will also have access to other persons within NHS D&G who can offer support regarding the PACS 2 process (via the patient's clinician).

A patient information leaflet will also be accessible 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.

DECLARATION OF INTERESTS

Relevant declarations of interest of all persons involved in the request (and the consideration of the request) should be captured as part of this system. The designated request form (Form PACS 2) has specific fields to be completed on this matter.

MANAGEMENT OF PACS 2 REQUESTS FOR PATIENTS FROM OTHER HEALTH BOARDS BEING MANAGED WITHIN NHS GG&C

The West of Scotland Health Boards have agreement on the management of PACS 2 within each others' Boards. The host Board is the one to which the patient has been referred from a home Board. The host Board and the host Board's Clinician assume responsibility for the patient's care. Two separate mechanisms will be applied, dependent on the cost per patient treatment or cost per patient per annum for continuing treatment:

(a) < £25,000
The standard NHS procedures will apply for the host board, with notification of the decision to the Medical Director of the home Board (or nominee) at the conclusion of the Panel review

(b) ≥ £25,000
An invitation will be extended to the Medical Director of the home Board (or their nominee) to participate as a Panel Member with full voting rights.

The decision of NHS host board Panel will be final and not subject to a further review at home Board level.
Following receipt of a decision from a PACS 2, the home Board has the opportunity of providing feedback to inform the process for future PACS 2 Panels.

The agreement described above is only relevant to West of Scotland health boards.

MANAGEMENT OF PACS 2 REQUESTS FOR PATIENTS REFERRED TO OTHER HEALTH BOARDS

In circumstances where a patient is referred to a clinician outwith NHS D&G for advice, but the responsibility of prescribing remains with the local clinician, NHS D&G PACS 2 processes will apply.

In circumstances where a patient is referred to a clinician outwith NHS D&G for full clinical responsibility/supervision of care, then NHS D&G will normally abide by the prescribing policies and decisions of the external Board/Trust, although completion of the NHS D&G PACS 2 documentation is considered good practice for audit and financial control purposes.

PACS 2 DATA CAPTURE AND REPORTING

NHS D&G is expected to maintain accurate and up to date information on PACS 2 requests and their decisions. Summary Management Reports of PACS 2 activity will be communicated to Scottish Government on a quarterly basis.

REVIEWING A PACS 2 DECISION

In the event where an agreement on a decision cannot be made locally, a National Review Panel has been established to independently look at the original decision made by NHS D&G and to consider whether due process had been correctly followed and/or that the decision reached is justified in light of the evidence submitted, to provide consistency for patients across Scotland.

It is the responsibility of the requesting clinician to submit an application to the National Review Panel, using Appendix 1 of Form PACS 2 and to ensure that a discussion takes place to confirm that the patient supports the decision to request a review.

National Review Panels will be convened on a monthly basis. Meetings will be held electronically (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 will be governed within Healthcare Improvement Scotland (HIS) who will facilitate support to the Panel. HIS personnel will not be part of the decision making process.

Additionally, 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.

An application to the National Review Panel must be made by the clinician, through a secure NHS Scotland email address to hcis.nap@nhs.net with a copy of the email sent to IPTRRegister@ggc.scot.nhs.uk. The clinician should also redact information relating to personal information in advance of it being submitted to the National Review Panel (via Healthcare Improvement Scotland), in line with data protection requirements.

Healthcare Improvement Scotland will notify the Chief Executive in NHS D&G that an review application has been made.

The review process will accommodate reviews on either of the following grounds:

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

A request for review will not be accepted solely because the patient or the clinician does not agree with the views or conclusions reached by the local panel. The National Review Panel would review the NHS D&G decision on this basis.

Where new evidence for the medicine emerges or if the original decision was based on a factual inaccuracy, the application should not be referred to the National Review Panel but the clinician should pursue a resubmission through the initial NHS D&G PACS 2 process. **No new evidence will be considered by the National Review Panel.**

The National Review Panel will follow the same decision making criteria as the local NHS Board Panel which is laid out in this guidance.

Evidence to the National Review Panel will be presented on the national standardised PACS paperwork (Form PACS2), which is the same paperwork which was considered by the original PACS 2 panel within NHS D&G

Outcome of Reviews

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 D&G 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 D&G 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.

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

The final decision is for NHS D&G to determine. NHS D&G 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 review.