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

OVERVIEW OF PROCESS

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

↓

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

↓

Yes
Follow the PACS Ultra-Orphan process

No
Follow the PACS 2 process below

Unsure of Status or which process to follow?
Contact Medicines Information for further advice (0141 211 4407)

↓

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

↓

Completed Form PACS 2 is submitted to relevant Chief of Medicine or appropriate email address.

These will differ dependent on sector and specialty and current contact details are specified on the front of the PACS 2 Request Form

***Decision making Criteria and Panel Considerations**

2. 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
3. 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.
4. The panel will, in addition, consider the wider benefit to the NHS

↓

PACS 2 Panel is convened by Chief of Medicine (or nominated person) and considers the submitted request against the Decision making Criteria for Acceptance within an appropriate timeline considering the urgency of the presenting case

The PACS 2 Panel will consider the request taking into account the decision making criteria and wider benefit to the NHS*

↓

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 IPTRRegister@ggc.scot.nhs.uk for collation and reporting to Scottish Government on a quarterly basis.

↓

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.nrp@nhs.net with a copy of the email sent to IPTRRegister@ggc.scot.nhs.uk

PURPOSE OF POLICY

This policy outlines the NHS GG&C 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.

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

1. GENERAL POLICY 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 6).

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. 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 making a negative decision.

2.4. 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.

2.5. 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).

2.6. Access to medicines which have been not recommended by SMC following a non-submission, or where a submission to SMC has yet to be made will be considered via the Individual Patient Treatment Request (IPTR) process (Link to Policy).

2.7. In NHS GG&C, the full PACS 2 process with review by a PACS 2 panel is only required for applications for applicable medicines where the basic NHS list price of the medicine exceeds £3,000 per patient treatment (or £3,000 per annum for continued or long-term treatment). This is to balance the resource required to implement PACS 2 against the benefit of a detailed process for low cost medicines. Medicines under this threshold will be subject to continuous review and management.

2.8. Where the medicine is a continuation of existing treatment there will be no requirement to submit an application via the PACS 2 process

2.9. Medicines Information will maintain a PACS List on the GGC Medicines Website (www.ggcmedicines.org.uk) which will highlight those medicines (from specialties other than Oncology or Haemato-oncology) which are required to be subject to the full PACS 2 panel consideration. However it should be noted that though this list will be updated regularly, not all medicines may be listed, especially if they have only recently received marketing authorisation. Therefore, where there is uncertainty, Medicines Information should be approached for specific advice (contact the team on (0141) 211 4407 or via email: ggc.medicines@ggc.scot.nhs.uk).

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 NHS GG&C. If there are no other appropriate clinicians locally, then experts from elsewhere in NHSScotland or from other parts of the UK can provide a supporting 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. Part C would still be required to be completed.

4. NATURE OF EVIDENCE

4.1. The 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 medicine 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 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 clinician-led and will typically consist of:
- Senior physician (e.g. Chief of Medicine, Clinical Director, Medical Director) or nominated deputy
- Senior pharmacist

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

5.3. Local arrangements should be in place for managing PACS 2 request for patients from other health boards (see section 11).

6. PANEL CONSIDERATIONS FOR DECISION MAKING

6.1. 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.

6.2. 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.

6.3. 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.

6.4. 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.

6.5. Appendix 1 provides panels with a decision making framework to assist in the consideration of the request and to help promote consistency in approach.

7. TIMESCALE FOR DECISION

7.1. 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.

7.2. 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.

8. DOCUMENTATION AND COMMUNICATION OF DECISION

8.1. 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.

8.2. A completed decision making framework tool (appendix 1) should form the basis of the content recorded in the *Main discussion points of pane*l section in the Part D of the PACS 2 request form

8.3. 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.

8.4. 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.

8.5. 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.

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

8.7. A copy of the PACS 2 request form detailing the outcome of the request should be emailed to IPTRRegister@ggc.scot.nhs.uk at the earliest opportunity for collation and use in routine reporting to Scottish Government.

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

8.9. 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.

8.10. NHS GG&C will ensure that local processes PACS 2 decisions are compliant with SFIs

9. SUPPORT FOR THE PATIENT

9.1. 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.

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

9.3. Each patient should be given a patient information leaflet (appendix 3) will 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.

10. DECLARATION OF INTERESTS

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

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

11.1. The West of Scotland Health Boards has an 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 (in this case NHS GG&C) 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:

- < £25,000
  The standard NHS GG&C procedures will apply, with notification of the decision to the Medical Director of the home Board (or nominee) at the conclusion of the Panel review
- ≥ £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.

11.2. The decision of NHS GG&C Panel will be final and not subject to a further review at home Board level.

11.3. 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.

11.4. NHS Highland requires patients referred to NHS GG&C for treatment to submit any PACS 2 requests directly to NHS Highland for consideration. Details for the PACS 2 process in NHS Highland, including the documentation to be used, can be accessed via the NHS Highland website (www.nhshighland.scot.nhs.uk).

11.5. The agreement described above is only relevant to West of Scotland health boards. When PACS 2 request for patients from other health boards are received in NHS GG&C, the relevant board should be linked with to establish the agreed mechanism for considering the request.

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

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

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

13. PACS 2 DATA CAPTURE AND REPORTING

13.1. NHS GG&C 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.

14. REVIEWING A PACS 2 DECISION

14.1. A National Review Panel has been established to independently look at the original decision made by NHS GG&C 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.

14.2. The review process will accommodate reviews on either of the following grounds:
- NHS GG&C had failed to follow due process and the situation cannot be resolved locally and/or
- NHS GG&C has reached a decision which could be deemed unreasonable in light of the evidence submitted.

14.3. 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 GG&C decision on this basis.

14.4. 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 GG&C PACS 2 process. No new evidence will be considered by the National Review Panel.

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

14.6. 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.

14.7. 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.

14.8. 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.

14.9. An application to the National Review Panel must be made by the clinician, through a secure NHS Scotland email address to hcis-nrp@nhs.net with a copy of the email sent to IPTRRegister@ggc.scot.nhs.uk. The clinician must 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.

14.10. Healthcare Improvement Scotland will notify the Chief Executive in NHS GG&C that a review application has been made.

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

14.12. Evidence to the National Review Panel will be presented on the original PACS 2 request form, which is the same paperwork which was considered by the original PACS 2 panel within NHS GG&C.

14.13. 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.

14.14. 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.

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

14.16. If the ground(s) of review is/are established then the case will be redirected back to the NHS GG&C 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.

14.17. 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.

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

14.19. The final decision is for NHS GG&C to determine. NHS GG&C 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.

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

APPENDIX 1: PACS 2 DECISION MAKING FRAMEWORK

APPENDIX 2: PACS 2 REQUEST FORM (FORM PACS 2)

APPENDIX 3: PACS 2 PATIENT INFORMATION LEAFLET

PACS 2 DECISION MAKING FRAMEWORK

To be used when considering requests for medicines for individual patient use whether licensed or unlicensed.

PACS 2 reference

(Where there are options Y/N please delete as appropriate, additional text space, using the grey text boxes are provided to include information which is not contained on the request form)

The panel should consider and note:

1. Clinical effectiveness

a) Has the clinician 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?
- ☐ NO: (if negative the process should not continue)
- ☐ YES:

b) Has the clinician 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 the SMC
- ☐ NO: (if negative the process should not continue)
- ☐ YES:

c) Is the patient expected to achieve a clinical benefit better than experienced by the population or sub populations, considered by the SMC e.g. are there any individual patient characteristics for example genetic sub-types where the clinical evidence is stronger?
- ☐ NO
- ☐ UNCERTAIN
- ☐ YES:

d) The strength of the available evidence (tick those that apply)
- ☐ SMC DAD
- ☐ Clinical Trials
- ☐ Additional case studies etc.

Additional relevant information e.g. Medicine Information Summary

e) Nature of the benefit, when will occur and duration of benefit?

f) Likely response rate and/ or attributable risk reduction and how this differs from the population reviewed by SMC (if applicable)?

2. Safety

a) Are there any safety considerations in using this medicine in this individual case e.g. side effects/ health risks and likelihood of occurrence?

3. Operational Impact

a) Service Impact – for example chair time, clinic capacity etc.

b) Other considerations e.g. administration, regimen, travel etc.

a) Nursing impact – training/ expertise/ capacity

b) Pharmacy impact – is it in stock/ used before/ protocols in place? Impact on aseptic services/ capacity?

c) Other factors – space, equipment, diagnostics, etc.

d) Does this contribute to any NHS priorities e.g. care closer to home, waiting time reduction etc.

4. Equity

a) Has this medicine been approved for use in the same or similar circumstances within your NHS Board?
☐ NO
☐ YES:

b) Has this medicine been approved for use in the same or similar circumstances within UK?
☐ NO
☐ YES:

5. Assessment of benefit to the NHS - health gain versus resource consumed

Impact of the requested treatment on healthcare e.g. Cost effectiveness and affordability, and the balance of benefit and risk in the context of what is the wider benefit to the NHS**?**

Signed:

Date:

PEER APPROVED CLINICAL SYSTEM (PACS) TIER TWO
REQUEST FORM AND DECISION RECORD

NHS Greater Glasgow and Clyde

Please note: This form is only to be used to request access to 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 SMC but the intended use is out with SMC restrictions; or
- is a medicine which has been submitted 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.

Notes for electronic completion:
This document can be completed by adding text to the grey text fields and by checking the tick boxes or selecting from drop-down boxes where applicable. It should be completed, saved and submitted electronically. Paper copies will not be accepted unless in exceptional circumstances.

The form is partitioned into 5 parts and 2 appendices:

- Parts A - C are to be completed prior to submission to the PACS Tier Two Panel.
- Part D is to be completed by the PACS Tier Two Panel only.
- Part E may be completed by the pharmacist on the PACS Tier Two panel with assistance from Medicines Information
- Appendix 1 is to be completed when referring a decision to the National Review Panel.
- Appendix 2 is for completion by the National Review Panel only.

Before submitting:

1. The requesting clinician completes parts A and B.
2. Part C is completed by another NHS clinician who is experienced in treating the condition for which the medicine is being requested.
3. Part D is completed by the PACS Tier Two Panel.
4. Appendix 1 is completed by the clinician in the event of referral to the National Review Panel.
5. Appendix 2 is completed by the National Review Panel.

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.

How to submit the request:

1. Send the completed form to relevant person or generic email inbox as follows:
    a. North Sector: chris.deighan@ggc.scot.nhs.uk
    b. South Sector: SouthSectorIPTRRequest@ggc.scot.nhs.uk
    c. Clyde Sector: Chris.Jones@ggc.scot.nhs.uk
    d. Oncology: IndividualPatientTreatmentRequest.Oncology@ggc.scot.nhs.uk
    e. Haematology and Haemato-oncology: IPTR.haematology@ggc.scot.nhs.uk
    f. Neurology: lesley.murray@ggc.scot.nhs.uk
    g. Paediatrics: alan.mathers@ggc.scot.nhs.uk
2. Following a decision by the panel, they will advise you of the outcome via email, attaching a copy of the completed paperwork, a copy of which should be filed in the patient's medical notes
3. For any queries relating to the process, contact the Medicines Policy and Guidance Team in Medicines Information (0141 211 4407 or ggc.medicines@ggc.scot.nhs.uk)

On reaching a decision:

1. The record of the PACS Tier Two decision must be documented in Part D of this form. The Chair of the PACS Tier Two panel should inform the requesting clinician of the decision by emailing a completed copy of Part D of this form within 5 working days, or if possible on the same day if clinical urgency demands this.
2. The Chair of the PACS Tier Two panel should ensure that a copy of the completed PACS Tier Two form and decision is emailed to the both the requesting clinician and IPTRRegister@ggc.scot.nhs.uk
3. 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.
4. The responsible clinician should discuss the outcome in detail, clarify future treatment options and discuss grounds for review, if appropriate, with the patient/patient's representative.
5. The patient's clinician should file a copy of the PACS Tier Two form and decision in the patient's case notes and retain a copy for future outcome reporting. (This paperwork will be required in the event of a referral to the National Review Panel or information requests from Scottish Ministers).

PART A: PACS TIER TWO REQUEST DETAILS

To be completed for all requests made by the requesting clinician

Patient's CHI Number:	**Patient Postcode:**
NHS board conducting PACS Tier Two: *(Please select from the drop-down list)*	NHS Greater Glasgow and Clyde
Patient's NHS board (if different from above): *(Please select from the drop-down list)*	Select from this list
Hospital/site where treatment is to be delivered or initiated: *(Please select from the drop-down list*	Select site from list
Requesting Clinician:	
Position held:	
Email address:	
Telephone/pager:	
Acute Services Sector/Division:	Select sector from list
Medicine and formulation: *(Include strength and dosage, refrain from using abbreviations. Please also include the SMC ID where known)*	
Intended indication: *(Also include any relevant positioning)*	
Clinical urgency: *(Please select from the drop-down list)*	Routine - response required within 4 weeks
Please give an explanation for your response regarding clinical urgency:	
How does this request relate to the SMC status of this medicine: *(Has the medicine not been recommended by SMC or is it awaiting/undergoing evaluation by the SMC, or is the intention to use the medicine outside of the restrictions on use imposed by SMC advice? Please select from the drop-down list)*	Medicine not recommended for use by SMC
Under which process(es) was medicine considered by SMC: *(This is the status of the medicine according to the SMC classification. Tick all options which apply)*	☐ Orphan ☐ End-of-life ☐ None

The patient understands the process:
(The clinician should explain the process to the patient (including the process for review) and ensure that the patient is content that the clincian will represent all of their clinical interests. Tools to support this may include using the national patient leaflet etc.

☐ Tick here to confirm

Multidisciplinary team support:
(If the patient is under the care of the multidisciplinary team the clinician has discussed the request and gained their agreement and support).

☐ Tick here to confirm

In accordance with the Code of Conduct of NHS Greater Glasgow and Clyde you are required to declare all interests you have in the pharmaceutical company which markets the medicine you are requesting on this form. It is possible that these may be checked against the national ABPI Interests database. Declared Interests do not directly impact on the process or decision, but are required to be noted to ensure transparency of process.

Declaration of interests:
(Please select from the drop-down list)

No interests to declare

- Personal interests may be payments/fees/resources etc that you have received personally from the company
- Non-personal interests may include payments/fees/resources etc. that your department has received from the company
- Specific interests are those that relate directly to the medicine you are requesting
- Non-specific interests are those that relate to the company, but not directly to the medicine you are requesting

Details of any declared interests:
(Where applicable)

By ticking this box I confirm that I am the clinician named above in charge of the patient's care: ☐ **Date:**

PART B: PACS TIER TWO CASE FOR PRESCRIBING

To be completed for all requests

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

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 Scotland for this condition and for the patient in question that these medicines are deemed unsuitable or have been found to be ineffective; and

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.

PLEASE NOTE: Only the information detailed on this form will be used to inform the panel's decision (and the review panel should that be required) and you will not have any further opportunity to clarify or provide further information. It should 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 noted above.

Information directly relating to referral criteria:

Please provide information to demonstrate that a reasonable attempt, or appropriate consideration, has been made to treat the patient with routinely available medicines normally of similar or better efficacy, including why they are deemed unsuitable for the patient or have been found to be ineffective.	
Considering any existing SMC advice (if available), please demonstrate the likelihood that the patient will achieve measurable clinical benefit (You should include all relevant factors such as performance status, previous response to other medicines and individual clinical characteristics that suggest that the patient will derive increased benefit. Please provide full citations for any clinical papers referred to)	

Further information relating to patient:

Previous treatment received by patient for this indication where available and why this is not being continued (Including approximate durations)	
Are there any supportive treatments, diagnostic tests or monitoring needed for this treatment? (provide detail, including whether the tests etc are routinely available)	
What are the potential adverse effects of the medicine requested?	
What outcome(s) would you propose to measure to ascertain a response to treatment? Detail the outcomes you would measure and how you would determine response (e.g. a response may be either an improvement in an outcome, or determined to be stabilisation)	
Under what circumstances would the requested treatment be reviewed or discontinued? Considering the outcomes that are proposed to be monitored, how would these be used to determine stopping criteria?	

Information directly relating to the medicine:

Relevant NICE advice (available from www.nice.org.uk) If the medicine has been accepted for use by NICE, please provide a reference (e.g. NICE TA number) and brief summary of guidance on use	
Relevant All Wales Medicines Strategy Group (AWMSG) (available from www.awmsg.org) If the medicine has been accepted for use by AWMSG, please provide the reference number and brief summary of guidance on use	
Any other information:	

PART C: PEER REVIEW

- 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. This clinician may be from within the same NHS board, but if there are no other clinicians with suitable expertise locally, then an expert 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 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, if not increased, compared to the population considered by SMC.

Name and position:	
NHS board/ Employing authority	Select from list
Peer review statement: The clinician should state his/her opinion relating to the request for this medicine for this condition, indicating whether they are supportive of the request and why (considering the notes above)	

In accordance with the Code of Conduct of NHS Greater Glasgow and Clyde you are required to declare all interests you have in the pharmaceutical company who market the medicine you are requesting on this form. It is possible that these may be checked against the national ABPI Interests database. Declared Interests do not directly impact on the process or decision, but are required to be noted to ensure transparency of process.

Declaration of interests: *(Please select from the drop-down list)*	No interests to declare

- Personal interests may be payments/fees/resources etc that you have received personally from the company
- Non-personal interests may include payments/fees/resources etc. that your department has received from the company
- Specific interests are those that relate directly to the medicine you are requesting
- Non-specific interests are those that relate to the company, but not directly to the medicine you are requesting

Details of any declared interests: *(Where applicable)*	

By ticking this box I confirm that I am the clinician named above: ☐ **Date:**

PART D: PACS TIER TWO DECISION RECORD

PLEASE NOTE: TO BE COMPLETED BY THE PACS TIER TWO PANEL ONLY

PACS TIER TWO PANEL MEMBERSHIP:

In accordance with Code of Conduct of NHS Greater Glasgow and Clyde each panel member is required to declare all interests they have in the pharmaceutical company who market the medicine you are requesting on this form.

	Name and position:	Declaration of interests:
Panel Chair (Typically a senior clinician)		No interests to declare
Panel member and position held:		No interests to declare
Panel member and position held:		No interests to declare
Panel member and position held:		No interests to declare
Panel member and position held:		No interests to declare

PACS TIER TWO PANEL DISCUSSION:

Date request received:		**Date of discussion:**	
How panel discussion was conducted: *(Please select from the drop-down list)*	Meeting		
Main discussion points of panel: *(Include how evidence and peer perspective were weighted)*			

DECISION OF REQUEST AND RATIONALE:

PACS TIER TWO PANEL DECISION: *(Please select from the drop-down list)*	**Supported**
Terms and conditions of acceptance (optional): *E.g. duration of treatment after which efficacy must be reviewed, monitoring schedule or stopping criteria. Where applicable, these terms should be clearly conveyed to the patient prior to commencing treatment.*	
Rationale for submission not supported: *Where a request has been rejected, the reasoning MUST be clearly stipulated in this section to allow the patient and clinician to be able to understand the rationale for the decision made.*	

Feedback to requesting clinician:
Where the request has been rejected, and there is scope for further review (e.g. there was insufficient information given to allow the panel to make a decision, please indicate what the clinician may do)

☐ Please provide further detail and resubmit as new request
☐ Other (provide additional comment in text box below)

By ticking this box I confirm that I am the PACS TIER TWO Panel Chair as detailed above: ☐ **Date:**

This form should be emailed to the requesting clinican within 5 working days of the panel decision **or if possible on the same day if clinical urgency demands this.**.

PART E: MEDICINE SUMMARY INFORMATION TO SUPPORT PACS 2 PANEL)

The Senior Pharmacist, as part of their role in the PACS 2 Panel, will facilitate a summary of the clinical evidence presented in this request (supported by Medicines Information). This section can be used to summarise information to facilitate further understanding of the information provided by the requesting clinician by the PACS 2 Panel.

Name of Medicine
Licensed Indication[1]
Indication under review
SMC Status http://www.scottishmedicines.org.uk/Home
Other relevant national Advice
National Institute for Health and Clinical excellence (NICE) http://www.nice.org.uk/Guidance/TA/Published
All Wales Medicines Strategy Group (AWMSG) http://www.wales.nhs.uk/sites3/page.cfm?orgid=371&pid=24773
SIGN Guidelines http://www.sign.ac.uk/
Other professional guidelines Note 3
Dose and Administration
Background of condition
Summary of evidence of comparative efficacy and adverse effects
Clinical Effectiveness
References
Author's details

Written by:	Date:
Reviewed by:	Date:

APPENDIX 1: APPLICATION TO NATIONAL REVIEW PANEL

Date of original application:		**Date of PACS TIER TWO Panel advice:**	

Basis for review request: *(NOTE: a review will not be accepted on the grounds that the patient or clinician does not agree with the views or conclusions reached)*	reached a decision which cannot be justified
Case for review request: *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.*	

By ticking this box I confirm that I am the clinician in charge of the patient's care and that the patient supports the decision to request a review: ☐ **Date:**

APPENDIX 2: NATIONAL REVIEW PANEL ADVICE

Please note: to be completed by the national review panel only

NATIONAL REVIEW PANEL MEMBERSHIP:

In accordance with the Code of Conduct of NHS Scotland each panel member is required to declare all interests they have in the pharmaceutical company who market the medicine you are requesting on this form.

	Name:	Declaration of interests:
Panel Chair and position held		Non-personal, non-specific interests declared
Panel Member and position held:		No interests to declare
Panel Member and position held:		No interests to declare
Panel Member and position held:		No interests to declare

NATIONAL REVIEW PANEL DISCUSSION:

Date request received:		**Date of discussion:**	

How review panel discussion was conducted: *(Please select from the drop-down list)*	Meeting
Basis for review request: *(NOTE: a review will not be accepted on the grounds that the patient or clinician does not agree with the views or conclusions reached)*	Select from list
Main discussion points of review panel:	

OUTCOME AND RATIONALE:

NATIONAL REVIEW PANEL FINDING *(Please select from the drop-down list)*	Select from list
Rationale: *(state why the panel feels a review is or is not necessary based on original evidence submitted)*	

By ticking this box I confirm that I am the Review Panel Chair as detailed above: ☐ **Date:**