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

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 4 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.
- 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:

Completed Form for PACS process must be submitted to the appropriate Key Contact detailed below:

Carol Walkinshaw
Business Manager, Pharmacy Service
E-mail: carol.walkinshaw@nhs.scot

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 submitting Clinician.
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)*	Select NHS Board
Patient's NHS board (if different from above): *(Please select from the drop-down list)*	Select NHS Board
Hospital/site where treatment is to be delivered/initiated:	
Requesting Clinician:	
Position held:	
Email address:	
Telephone/pager:	
Acute Services Division:	
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)*	
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)*	Select SMC recommendation
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 (*insert local Health Board)* 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)

- 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 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

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 referral 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 NHS Board
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.	

In accordance with the Code of Conduct of NHS (*insert local Health Board)* 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)*	

- 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 (*insert local Health Board*) 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)		
Panel member #2:		
Panel member #3:		
Panel member #4:		
Panel member #5:		
Panel member #6:		
Panel member #7:		

PACS TIER TWO PANEL DISCUSSION:

Date request received:		**Date of discussion:**	
How panel discussion was conducted: *(Please select from the drop-down list)*			
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)*	
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.

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)*	
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 (insert local Health Board) 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		
Panel Member and position held:		
Panel Member and position held:		
Panel Member and position held:		

NATIONAL REVIEW PANEL DISCUSSION:

Date request received:		**Date of discussion:**	
How review panel discussion was conducted: *(Please select from the drop-down list)*			
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)*			
Main discussion points of review panel:			

OUTCOME AND RATIONALE:

NATIONAL REVIEW PANEL FINDING *(Please select from the drop-down 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:**