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| **PEER APPROVED CLINICAL SYSTEM (PACS)** |  |

**Please note: PACS is currently a process being piloted by NHS Boards on behalf of Scottish Government,**

This form is only to be used to request access to a licensed medicine and indication that has been designated ultra-orphan as part of its evaluation by the Scottish Medicines Consortium (SMC) and where the medicine has been subsequently not recommended for use in NHS Scotland by the SMC.

**Notes for electronic completion:**

This word document can be completed by adding text to the grey text fields and by checking the tick boxes where applicable.

* Requesting consultant completed sections 1 to 5
* A clinician experienced in the management of the condition being treated then must indicate his/her support of the request by completing section 6 of this document.
* Upon completion of sections 1 to 6, the form should be saved and emailed to the Acute Medical Director who will convene a PACS panel and complete the decision record section of the form; seeking clarification from the requesting consultant should further information or amendments be required.
* The form will then be passed back to the requesting consultant, who should ensure a copy of the completed record is scanned into the patients electronic patient record (Clinical Portal)

**For advice on the completion of this form or relating to the PACS process, please contact the onsite Head of Pharmacy.**

**Section 1: Patient & location details**

|  |  |  |  |
| --- | --- | --- | --- |
| **Patient’s CHI Number:** |  | **Patient Postcode:** |  |

|  |  |
| --- | --- |
| **Ward or Department:** |  |

|  |  |
| --- | --- |
| **Hospital where treatment is to be delivered/initiated:**  (please select from the drop-down list) | Treatment within Hairmyres:  Treatment within Monklands:  Treatment within Wishaw General: |

|  |  |
| --- | --- |
| **Patient’s residing Health Board:**  (Please select from the drop-down list) |  |

**Section 2: consultant & directorate details**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of Consultant and position:** |  | **Page/contact number:** |  |

|  |  |
| --- | --- |
| **Directorate:**  (please choose from drop-down list) |  |

**Section 3: medicine details & URGENCY**

|  |  |
| --- | --- |
| **Medicine and formulation:** |  |
|  |  |
| **Intended indication:** |  |
|  |  |
| **Clinical urgency:** |  |

**Section 4: case for prescribing**

*The prescribing clinician should make the case for the prescribing of this medicine focussing on the measurable benefit that the medicine would deliver for the individual patient. This case should focus on the clinical evidence, including drawing on any experience in clinical practice. The prescribing clinician should also set out proposals for monitoring of clinical outcomes.  These would be expected to be shared with the individual patient and may be shared with others in NHS Scotland (including SMC) to inform future decision making.*

|  |  |
| --- | --- |
| **Please summarise the case for prescribing this medicine for this patient.**  Aim to include in your response:   * a brief treatment history * an overview of the evidence base * Any personal experience of using this medicine |  |
|  |  |
| **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) |  |
|  |  |
| **Proposed review schedule to be reported to the PACS Panel:**  This should detail the outcomes to be measured and reporting frequency to the approval panel.  Please consider stopping criteria and how these will be discussed with the patient. |  |
|  |  |
| **Any other information:** |  |

**section 5: REQUESTING consultant CONFIRMATION & declaration of interests:**

**Prior to signing and submitting the form, the requesting consultant should clarify that the patient has been advised of the following:**

|  |  |
| --- | --- |
| The patient has had the PACS process explained to them and has been directed to a source of further information |  |

**INTERESTS IN THE PHARMACEUTICAL COMPANY MANUFACTURING THE MEDICINE REQUESTED:**

In accordance with the [NHS Lanarkshire Code of Conduct](http://www.staffnet.ggc.scot.nhs.uk/Corporate%20Services/Board%20Admin/Documents/Code%20of%20Conduct%20for%20Staff%20June%202013%20-%20Final.doc), you are required to declare all previous personal-specific interests and any other current interests (within the last 12 months) you have in the pharmaceutical company who market the medicine you are requesting on this form.

|  |  |
| --- | --- |
| **If you have no interests to declare, tick here:** |  |

Otherwise, tick one of the four boxes below that best describes the type of interest(s) (e.g. personal, specific) and give brief detail on the nature of this in the box below.

|  |  |  |
| --- | --- | --- |
|  | **SPECIFIC INTERESTS**  These are interests relate directly to the medicine you are requesting | **NON-SPECIFIC INTERESTS**  These are interests that relate to the company, but not directly to the drug you are requesting |
| **PERSONAL INTERESTS**  Payments/fees/resources etc that you have received personally from the company |  |  |
| **NON-PERSONAL INTERESTS**  Payments/fees/resources etc that your department has received from the company |  |  |
|  |  |  |
| **DETAILS OF INTERESTS:**  Give details of your interests in this section: |  | |

**CONSULTANT CONFIRMATION:**

By the ticking of the following box you are confirming your position in charge of the patients care. The PACS application can then be submitted via email.

|  |  |  |  |
| --- | --- | --- | --- |
| **By ticking this box I confirm that I am the consultant named in section 2:** |  | **Date:** |  |

**section 6: PEER support FOR proposed treatment**

* **This section is mandatory for PACS. It should be completed by another senior clinician experienced in treating the condition for which the medicine is being requested for.**
* **This clinician may be from within NHS Lanarkshire, but if there are no other appropriate clinicians locally, experts from elsewhere in NHS Scotland or the UK can provide a supporting statement.**
* **If the supporting clinician cannot directly provide support using this form, please attach a copy of any communications which indicate their support (e.g. emails) with this form when submitted to the Acute Medical Director.**

|  |  |
| --- | --- |
| **Name and position:** |  |
|  |  |
| **Health board/ Employing authority** |  |

|  |  |
| --- | --- |
| **Statement of support:**  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. |  |
|  |  |
| **Comments relating to reporting schedule:**  Are the outcomes being measured appropriate and are there any additional outcomes which may be suitable to monitor? |  |

**INTERESTS IN THE PHARMACEUTICAL COMPANY MANUFACTURING THE MEDICINE REQUESTED:**

In accordance with the [NHS Lanarkshire Code of Conduct](http://www.staffnet.ggc.scot.nhs.uk/Corporate%20Services/Board%20Admin/Documents/Code%20of%20Conduct%20for%20Staff%20June%202013%20-%20Final.doc), you are required to declare all previous personal-specific interests and any other current interests (within the last 12 months) you have in the pharmaceutical company who market the medicine you are requesting on this form.

|  |  |
| --- | --- |
| **If you have no interests to declare, tick here:** |  |

Otherwise, tick one of the four boxes below that best describes the type of interest(s) (e.g. personal, specific) and provide brief detail on the nature of this in the box below.

|  |  |  |
| --- | --- | --- |
|  | **SPECIFIC INTERESTS**  These are interests relate directly to the medicine you are requesting | **NON-SPECIFIC INTERESTS**  These are interests that relate to the company, but not directly to the drug you are requesting |
| **PERSONAL INTERESTS**  Payments/fees/resources etc that you have received personally from the company |  |  |
| **NON-PERSONAL INTERESTS**  Payments/fees/resources etc that your department has received from the company |  |  |
|  |  |  |
| **DETAILS OF INTERESTS:**  Give details of your interests in this section: |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| **By ticking this box I confirm that I am person named above:** |  | **Date:** |  |

|  |  |
| --- | --- |
| **PACS Decision Record** | NHSL logo.jpg |

**PLEASE NOTE: THIS POINT FORWARD TO BE COMPLETED BY THE PACS PANEL ONLY**

**Section A: PACS Details**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Patient’s home NHS Board:** |  | | | | |
|  |  | | | | |
| If other health board, has the panel had representation from the patient’s home board? | | | | Yes:  No: |  |
|  |  | | | | |
| **Date request Received:** |  | **Date of PACS Panel Decision:** |  | | |

**Section B: pacs panel & declaration of interests**

**INTERESTS IN THE PHARMACEUTICAL COMPANY MANUFACTURING THE MEDICINE REQUESTED:**

In accordance with the [NHS Lanarkshire Code of Conduct](http://www.staffnet.ggc.scot.nhs.uk/Corporate%20Services/Board%20Admin/Documents/Code%20of%20Conduct%20for%20Staff%20June%202013%20-%20Final.doc), each panel member is required to declare all previous personal-specific interests and any other current interests (within the last 12 months) they have in the pharmaceutical company who market the medicine you are requesting on this form.

|  |  |  |  |
| --- | --- | --- | --- |
| **Acute Medical Director (Chair):**  (or nominated deputy) |  | No interests:  Interests declared (detail below): |  |
|  |  |  |  |
| **Senior Pharmacist:** |  | No interests:  Interests declared (detail below): |  |
|  |  |  |  |
| **Other relevant Clinical Adviser:** |  | No interests:  Interests declared (detail below): |  |
|  |  |  |  |
| **If non-NHS L patient, name and position of home board representation (if required):** |  | No interests:  Interests declared (detail below): |  |
|  |  |  |  |
| **Details of any declared interests noted by panel members:** |  | | |

**Section C: pacs decision**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1. **Request and review proposal approved:** | |  | | | |
| 1. **Further expert input required or revision to outcome reporting proposal before approval can be granted:**   (Further detail must be provided in the question below if this is selected) | | |  | |
| **Details of requirements to be met prior to approval:** | | | |
|  | | |

1. **Refused based on risk benefit profile for the patient:**

**Section D: PACS panel chair CONFIRMATION**

**Acute Medical Director (or nominated deputy) confirmation on behalf of PACS panel:**

|  |  |  |  |
| --- | --- | --- | --- |
| **By ticking this box I confirm that I am the PACS Panel Chair as detailed in section B**: |  | **Date:** |  |

**WHAT TO DO WITH COMPLETED FORM FOLLOWING DECISION:**

1. Inform the requesting consultant of the decision by returning the completed form as soon as possible
2. The PACS Panel Chair should retain a copy for audit purposes
3. The Chair of the PACS panel should ensure that a copy of the completed PACS form and decision is emailed to the Pharmacy Admin Office Kirklands ([isobel.marhsall@lanarkshire.scot.nhs.uk](mailto:isobel.marhsall@lanarkshire.scot.nhs.uk))
4. The patient’s consultant should file a copy of the PACS form and decision in the patient’s case notes
5. If the patient is from a board other than NHS Lanarkshire, inform the home board of the decision (if they have not actively been involved) and provide a copy of the completed documentation.