|  |  |
| --- | --- |
| **Unlicensed Medicine / Off-Label Request** | NHSGGC - logo - black |

**Notes for completion:**

* This form should only be used when unlicensed medicines or the high-risk off-label use of licensed medicines are considered for use.
* The requesting consultant should complete sections 1 to 6 of the form as fully as possible. The form consists of grey text fields which expand when typed in, check boxes and drop-down lists to make completion clear and fast.
* It is strongly recommended that this eForm is completed and transferred electronically.
* The form should then be emailed or sent to the relevant Clinical Director or Associate Medical Director (AMD) depending on the cost of the medicine. If the medicine requested costs in excess of £3,000 per patient treatment, the relevant Associate Medical Director (AMD) and General Manager (GM) (or their nominated deputy) will need to provide Directorate Approval. If <£3,000, email the relevant Clinical Director will be able to consider the request. Seek advice from Pharmacy if you are unsure.
* Once a decision about the use of the medicine has been made by the relevant person(s), the form will be returned to the requesting consultant.
* All sections must be completed by all relevant persons prior to prescribing/requesting medicine to ensure that delays in treatment are minimised.
* The requesting consultant should then send the completed form accompanied by the prescription/medicine request to the relevant pharmacy department prior to supply being made. Acute pharmacy departments will have a designated pharmacist who deals with unlicensed medicines that can be contacted for advice and who will authorise the supply from a pharmacy perspective.
* A copy of the original form, detailing the decision, should be filed in the patient’s case notes.

**BEFORE COMPLETING, CHECK THAT YOU ARE USING THE RIGHT FORM FOR YOUR TYPE OF REQUEST**

**IF YOU ARE UNSURE, SEEK ADVICE FROM PHARMACY OR MEDICINES INFORMATION**

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 of the board in where treatment is to be delivered) | Treatment within NHSGGC:  Treatment within NHS AA:  Treatment within NHS L:  Treatment within NHS FV: |

|  |  |
| --- | --- |
| **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: |  |

|  |  |
| --- | --- |
| **Acute services division:**  (please choose from drop-down list) |  |

Section 3: medicine details & Urgency

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

Section 4: category of request

|  |  |
| --- | --- |
| 1. The intended use of the medicine is outside of the marketing authorisation for a licensed medicine (off-label prescribing) |  |
|  |  |
| 1. The medicine is not yet licensed for use in the UK and the request is a compassionate use request |  |

NB: If the medicine is a licensed medicine that is being used out with its marketing authorisation, or the medicine is unlicensed, the prescriber carries the responsibility of the patient’s welfare and may be called to justify his/her actions in the event of an adverse reaction.

Section 5: Supporting information

|  |  |
| --- | --- |
| This particular use of this medicine is recommended in a relevant SIGN Guideline |  |
|  |  |
| This particular use of this medicine is recommended in a relevant NICE Guideline: |  |
|  |  |
| This particular use of this medicine is recommended in other guidance (please provide further information below): |  |

|  |  |
| --- | --- |
| Please provide further details: |  |

|  |  |
| --- | --- |
| Clinical rationale for use in this patient, including expected outcome:  (please submit any clinical papers referenced with this form) |  |

|  |  |
| --- | --- |
| Previous treatment for this indication:  (Including duration) |  |

|  |  |
| --- | --- |
| Expected duration of treatment: |  |

|  |  |
| --- | --- |
| Estimate of expected cost:  (indicate what cost is for e.g. treatment period or per year) | IF THE ESTIMATED COST OF PRESCRIBING THIS MEDICINE IS IN EXCESS OF £3,000 PER PATIENT EPISODE, THEN ASSOCIATE MEDICAL DIRECTOR APPROVAL IS REQUIRED. |

|  |  |
| --- | --- |
| Are there any supportive treatments needed for this treatment? |  |

|  |  |
| --- | --- |
| Reason why a licensed drug (or drug licensed for this indication) not selected: |  |

|  |  |
| --- | --- |
| What are the risks to the patient if they DO receive this treatment?  (include any side effects or toxic effects that may be expected) |  |

|  |  |
| --- | --- |
| What will be used if this drug is not authorised? |  |

|  |  |
| --- | --- |
| Planned review:  (please state when and how response to treatment will be measured) |  |

|  |  |
| --- | --- |
| Where is the treatment to be delivered and does it impact on other areas?  (e.g. within acute sector or intended to be continued in primary care) indicate whether the use of this medicine will impact on other directorates or on Primary Care) |  |

section 6: CONFIRMATION, CHECKLIST & declaration of interests:

INTERESTS IN THE PHARMACEUTICAL COMPANY MANUFACTURING THE MEDICINE REQUESTED:

In accordance with the [NHS GGC 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:

Rather than require a handwritten signature which requires the form to be printed, the ticking of the following confirmation will be regarded as a signature, allowing the IPTR to be submitted via email.

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

section 7: pharmacy comment

This section is recommended to be completed for specialist oncology requests by the local pharmacist where the treatment is to be delivered. It should be used to provide any relevant information relating to drug availability or potential service delivery issues associated with this request. The pharmacist may also wish to ensure that the correct form and category have been selected.

This statement is not intended for the pharmacist to detail their views on the request.

|  |  |
| --- | --- |
| Name and position: |  |

|  |  |
| --- | --- |
| Statement: |  |

INTERESTS IN THE PHARMACEUTICAL COMPANY MANUFACTURING THE MEDICINE REQUESTED:

In accordance with the [NHS GGC 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: |  | |

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

|  |  |
| --- | --- |
| **ULM Request Decision Record** | NHSGGC - logo - black |

PLEASE NOTE: THIS POINT FORWARD TO BE COMPLETED BY AMD/CLINICAL DIRECTOR

NOTES:

1. Requests for treatment costing <£3,000 per patient treatment can be authorised by the relevant Clinical Director for the specialty. However, all requests costing in excess of £3,000 per patient treatment must be authorised at directorate level by the relevant Associate Medical Director and General Manager.If the use of this medicine will have an impact on any other directorates or on Primary Care, then this should be discussed with the relevant person(s) prior to the medicine being prescribed.

**Section A: ULM request Details**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Patient’s home NHS Board:** |  | | | | |
|  |  | | | | |
| If other health board, does the treatment cost meet the £25,000 threshold that would require the home board to be informed? | | | | Yes:  No: |  |
|  |  | | | | |
| **Date Request Received:** |  | **Date of Decision:** |  | | |

**Section B: Clinical Director / Amd declaration of interests**

INTERESTS IN THE PHARMACEUTICAL COMPANY MANUFACTURING THE MEDICINE REQUESTED:

In accordance with the [NHS GGC 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: |  | |

**Section C: decision**

|  |  |  |  |
| --- | --- | --- | --- |
| **Accepted:** |  | **Rejected:** |  |

**Section D: Terms of acceptance (where applicable)**

|  |  |
| --- | --- |
| **Terms and conditions of acceptance:**  (e.g. duration of treatment after which efficacy must be reviewed and reported on to the panel) |  |

**Section E: reason for rejection (where applicable)**

|  |  |
| --- | --- |
| **Please provide details as to why the non-Formulary request was rejected:** |  |

**Section f: clinical director /amd CONFIRMATION**

Clinical Director / Associate Medical Director (or nominated deputy) confirmation:

Rather than require a handwritten signature which requires the form to be printed, the ticking of the following confirmation will be regarded as a electronic signature.

|  |  |
| --- | --- |
| **Name and position:** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| By ticking this box I confirm that I am the Clinical Director/AMD named above: |  | Date: |  |

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

1. Inform the requesting consultant of the decision by returning the completed form
2. A copy of the completed request and decision is required to be sent or emailed to the Formulary Team ([ggcprescribing@ggc.scot.nhs.uk](mailto:ggcprescribing@ggc.scot.nhs.uk))
3. The Clinical Director/AMD should retain a copy for audit purposes
4. The patient’s consultant should file a copy of the request and decision in the patient’s case notes