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

**Notes for completion:**

* This form should only be completed when considering use of unlicensed medicines or use of licensed medicines in a high-risk off label manner.
* 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.
* 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 Chief of Medicine (CoM) depending on the cost of the medicine. If the medicine requested costs in excess of £3,000 per patient treatment, the relevant CoM and General Manager (GM) (or their nominated deputy) will need to provide approval. If <£3,000, 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. .
* A copy of the eform, detailing the decision, should be filed in the patient’s clinical portal records under correspondence

**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 & division 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: |  |
|  |  |
| This medicine is an Advanced Therapy Medicinal Product: | Yes  No |
|  |  |
|  | If Yes – state type of ATMP: Gene Therapy  Somatic Cell Therapy  Tissue Engineered Product |
|  |  |
| This medicine is a gene therapy product, eg some vaccines, CAR-T, delivery is via a viral vector. | Yes  No |
|  |  |
|  | If Yes – requesting clinician please contact Lead Pharmacist Research & Innovation for advice on any additional risk assessment required. |
|  |  |
| 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 |  |

Section 5: Supporting information & declaration of interests

|  |  |  |
| --- | --- | --- |
|  | |  |
| 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: |  |

|  |  |
| --- | --- |
| 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 division or intended to be continued in primary care) indicate whether the use of this medicine will impact on other services or on Primary Care) |  |

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 decisions, but are required to be noted to ensure transparency of process.

|  |  |
| --- | --- |
| **Declaration of interests:** |  |

* Personal interests may be payment/ 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 supporting

|  |  |
| --- | --- |
| Details of any declared interests:  (where applicable): |  |

|  |  |  |  |
| --- | --- | --- | --- |
| By ticking this box I confirm that I am the person named in section 5: |  | Date: |  |

section 6: peer review & declaration of interests

|  |  |  |  |
| --- | --- | --- | --- |
| Name and position: |  | Page/contact number: |  |

|  |  |
| --- | --- |
| **NHS board/ Employing authority** |  |

|  |  |
| --- | --- |
| 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 : |  |

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|  |  |
| --- | --- |
| **Declaration of interests:** |  |

* Personal interests may be payment/ 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 supporting
* Non-specific interests are those that relate to the company, but not directly to the medicine you are supporting

|  |  |
| --- | --- |
| Details of any declared interests:  (where applicable): |  |

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| --- | --- | --- | --- |
| By ticking this box I confirm that I am the person named in section 6: |  | Date: |  |

section 7: pharmacy comment & declaration of interests

This section is recommended to be completed 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: |  |

|  |  |
| --- | --- |
| 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 CHIEF OF MEDICINE APPROVAL IS REQUIRED. |
|  |  |
| Product quality risk assessment:  (please refer to local pharmacy risk assessment procedures) |  |
|  |  |
| If the requested product is an ATMP or CAR-T, please check that the requesting clinician has initiated the relevant assessment process. | |
|  |  |
| Final Assessment of submitted request: |  |
|  |  |

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|  |  |
| --- | --- |
| **Declaration of interests:** |  |

* Personal interests may be payment/ 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 requested
* Non-specific interests are those that relate to the company, but not directly to the medicine requested

|  |  |
| --- | --- |
| Details of any declared interests:  (where applicable): |  |

|  |  |  |  |
| --- | --- | --- | --- |
| By ticking this box I confirm that I am the person named in section 7: |  | Date: |  |

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

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

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 Chief of Medicine (CoM). 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 / CoM declaration of interests**

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 supporting 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 decisions, but are required to be noted to ensure transparency of process.

|  |  |
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| **Declaration of interests:** |  |

* Personal interests may be payment/ 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 requested
* Non-specific interests are those that relate to the company, but not directly to the medicine requested

|  |  |
| --- | --- |
| Details of any declared interests:  (where applicable): |  |

|  |  |  |  |
| --- | --- | --- | --- |
| By ticking this box I confirm that I am the person named in section F below: |  | Date: |  |

**Section C: decision**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Clinical assessment** | **Accepted:** | | **Rejected:** | |  |  | | --- | --- | | Date: |  | |
|  | | | | |
|  | | | | |
|  | | | | |
|  | | | | |
| **If ATMP request, clinical staff to complete the following:** | | | | |
|  | | | | |
| GMSC assessment | **Accepted:** | | **Rejected:** | |  |  | | --- | --- | | Date: |  | |
|  | | | | |
| Name of GMSC contact: | |  | | |
|  | | | | |
| Name of staff member documenting  GMSC decision: | |  | | |
|  | | | | |

**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: DECISION BY pmg (where applicable)**

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

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

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

**Section g: clinical director /COM CONFIRMATION (where applicable)**

Clinical Director / CoM (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/CoM 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 Medicines Policy & Guidance Team ([IPTRRegister@ggc.scot.nhs.uk](mailto:IPTRRegister@ggc.scot.nhs.uk) )

For ATMPs the clinician documenting the GMSC decision should send a copy of the eform including all relevant decisions to the

Medicines Policy & Guidance Team. ([IPTRRegister@ggc.scot.nhs.uk](mailto:IPTRRegister@ggc.scot.nhs.uk) )

1. The Clinical Director/ CoM should retain a copy for audit purposes.
2. The patient’s consultant should save a copy of the eform including the decision in the patient’s clinical portal records under correspondence.cal portal records under correspondence