**Drug - Individual Funding Request (IFR) form**

(This form is to be used for drug requests where the requesting clinician is of the opinion this individual patient has an exceptional healthcare need and is presenting a case for clinical exceptionality)

**(PLEASE ENSURE APPENDIX A – EVIDENCE PROFORMA IS COMPLETED AND SUBMITTED WITH THE REQUEST ALONG WILL ALL ARTICLES/SUPPORTING INFORMATION IN FULL TEXT)**

**ANY INCOMPLETE FORMS THAT PROVIDE INSUFFICIENT INFORMATION OR HAVE DOCUMENTS MISSING WILL BE REJECTED AND RETURNED TO THE REQUESTER**

**PLEASE ENSURE SECTION “G” IS FULLY COMPLETED FOR REQUESTS FOR CONTINUATION OF TREATMENT**

**ALL REQUESTS MUST BE COMPLETED BY THE CLINICIAN OR CLINCIAL TEAM WHO IS TREATING THE PATIENT**

**Before completing and submitting this form, you MUST first consider the following:**

* **Has the request been approved by the Drugs & Therapeutic Committee (D&TC) or equivalent?**

If NO, do not continue with this request until approval has been sought

* **Is this a request for a treatment that is currently commissioned by NHS England?**

If YES, do not continue and redirect your request to NHS England.

If unsure please see <https://www.england.nhs.uk/publication/manual-for-prescribed-specialised-services/> or email [england.ifr@nhs.net](mailto:england.ifr@nhs.net) for advice

* **Are there likely to be any other patients with similar clinical circumstances across Greater Manchester who could also benefit from the treatment you are requesting?**

If YES, a clear arguable case for exceptionality needs to be presented to demonstrate how this patient is clinically different to the cohort.

* **Is it likely that the claims of exceptionality could also apply to other patients within the cohort?**

If YES, alternative routes will need to be discussed for this intervention

**Please refer to the GM IFR Team Operational Policy for more details on clinical exceptionality** [GM IFR Operational Policy](https://gmeurnhs.co.uk/Docs/Other%20Policies/GM%20EUR%20Operational%20Policy.pdf)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Date of approval given by D & TC or equivalent** | Click or tap to enter a date.  *(please also provide a copy/extract of the D&TC meeting notes where available)* | | | | |
| **CONTACT DETAILS** | | | | | |
| **Requesting clinician details**  **This form should only be completed and submitted by the treating clinician** | **Name:** | |  | | |
| **Designation:** | | | | |
| **Organisation:** | | | | |
| **Contact phone number:** | | | | |
| **Secure email: (e.g. @nhs.net):** | | | | |
| **Patient details** | **Name:** | | | | |
| **Address :** | |  | | |
| **Date of birth:** | | | | |
| **NHS number:** | | | | |
| **GP practice and post code:** | | |  | |
| **You MUST NOT use any patient, clinician or provider identifiers in the remainder of this form.**  **If any details are included in the remainder of the form, it will be returned for redaction to be undertaken by the requestor.**  **Before a request is considered by the GM Individual Funding Request (IFR) Panel any factors which are non-clinical or non-relevant clinical factors may be redacted.** | | | | | |
| 1. **Intervention Requested** | | | | | |
| 1. **Details of treatment for which funding is requested** | Drug name  (please include generic and brand if applicable) | | |  | |
| Dose and routine of administration | | |  | |
| Where will the treatment take place (e.g. OPD, day case, home, etc) | | |  | |
| Frequency and expected duration of treatment | | |  | |
| 1. **Is the request time critical? If so, when should the treatment commence?**   ***(Please see*** [GM IFR Operational Policy](https://gmeurnhs.co.uk/Docs/Other%20Policies/GM%20EUR%20Operational%20Policy.pdf) ***for more details, including definition of urgency)*** | Choose an item.  Click or tap to enter a date.  If the case is urgent,please state the clinical reason why:  ***Note: Treatment undertaken before the application is received will not be funded retrospectively but if further or ongoing treatment is needed, it will be considered for approval*** | | | | |
| 1. **Is this trust/hospital/provider commissioned to provide the requested intervention?**   **Is the treatment excluded from tariff?**  [**https://gmmmg.nhs.uk/guidance/high-cost-drugs/**](https://gmmmg.nhs.uk/guidance/high-cost-drugs/) | Choose an item.  Choose an item. | | | | |
| 1. **Is there an existing GMMMG commissioning statement for this treatment?** | Choose an item.  *If yes, please provide details* | | | | |
| 1. **If there is not an existing GMMMG commissioning statement for this healthcare need / treatment, is there any other relevant guidance e.g. NICE TA** | Choose an item.  *If yes, please provide details and links were possible* | | | | |
| 1. **Does the patient meet the GMMMG or other relevant guidance for this healthcare need / treatment?**   **If no, please explain why the patient does not meet the guidance.** | Choose an item. | | | | |
| 1. **Healthcare need identified / Past Medical History**   ***An exceptional health care need focuses on the actual “health problem” of the patient rather than the individual patient themselves. An exceptional health care need may include a rare / highly unusual / not typical presentation of a health condition a patient is diagnosed with*** | | | | | |
| 1. **With the above description in mind, do you consider this patient to have an exceptional healthcare need?** | Choose an item. | | | | |
| 1. **Healthcare need identified** *(for which the intervention is being requested)*   **Date healthcare need was identified or diagnosed**  **BMI (if relevant to the request)** | Click or tap to enter a date.  Height       Weight       BMI  Date BMI calculated Click or tap to enter a date. | | | | |
| 1. **Does the patient have any relevant past medical history?**   *Please include any past disease activity scores or other clinical measures where appropriate or any tests investigations that have been carried out* |  | | | | |
| 1. **What is the patient’s current clinical presentation?**   *Please summarise the current status of the patient in terms of their QoL for example performing activities of daily living and any relevant disease scores or other clinical measures where appropriate* |  | | | | |
| 1. **Is the patient currently waiting for any investigations or other procedures?** | Choose an item.  *If yes, please provide details* | | | | |
| 1. **Is there a standard treatment pathway for this treatment / health care need?**   **(If there is no standard treatment pathway, please state this)** | Choose an item.  *Please provide reference to / copy of the standard treatment pathway if relevant* | | | | |
| 1. **Was the standard pathway followed?**   **If the standard pathway was not followed, please explain reasons why** | Choose an item. | | | | |
| 1. **What were the outcomes of all interventions tried to date?**   **Include all ongoing and stopped treatments\* and treatments not tried (including reasons, e.g. contraindication) \*reasons for stopping may include treatment completed, inadequate/ lack of clinical response/ disease progression, adverse effects /intolerance** | | | | | |
| Please provide all the information requested to avoid delays in processing this request   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Treatment name | Date started (please state frequency) | Response | Treatment duration | Reason(s) for stopping | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | | | | | | |
| 1. **Consideration of exceptionality for the healthcare need**   *To meet the definition of ‘exceptional clinical circumstances’ your patient must demonstrate that they are both:*   * *Significantly different clinically to the group of patients with the condition in question and at the same stage of progression of the condition.*   ***AND***   * *Likely to gain significantly more clinical benefit than others in the group of patients with the condition in question and at the same stage of progression of the condition.*   *Further details can be found at:* [*GM IFR Operational Policy*](https://gmeurnhs.co.uk/Docs/Other%20Policies/GM%20EUR%20Operational%20Policy.pdf) | | | | | |
| 1. **How common is this patient’s healthcare need?**   *Please provide the source/references for the stated incidence & prevalence and attach full text articles in your submission* | Incidence: state number of ‘new’ patients expected to have this condition per 100,000 population per year:  Prevalence: state the number of patients expected to have this condition per 100,000 population at any one time: | | | | |
| 1. **How many patients present with this condition within your service?** | *(Please include time frame e.g. monthly / yearly)* | | | | |
| 1. **Which areas of exceptionality from the list below do you believe apply to your patient when considering their exceptional healthcare need?**   *Note to requesting clinician: Please provide as much detail as possible in this section to enable the GM IFR Team to fully assess this patient’s exceptional healthcare need.* | | | | | |
| 1. **Failure to respond to standard care**  * *Is the patient’s inability to respond to, or be provided with, the usual treatment a genuinely exceptional circumstance, which lies outside the natural history of the condition and is not characteristic of the relevant group of patients with the condition.*  1. **Severity**  * **I***s there evidence that the patient’s presentation lies outside the normal spectrum for that condition?* * *Is there evidence that the patient has progressed to a very severe form of the condition much more rapidly than the range of progression that is documented and usually observed within the natural history of the condition?* * *How is the patient expected to benefit from the treatment being requested and in what quantifiable way?* * *Is there evidence that the impact of the condition on this patient's health is significantly greater than its impact on the rest of the cohort of patient’s?* * *Is there a plausible argument that the severity of the condition is prognostic of good response to treatment?*  1. **Genotypes**  * *Is there evidence of the prevalence of the genotypes within this patient group?* * *The requesting clinician will need to show how the specific genotype would make the patient different to others in terms of clinical management and be able to benefit from the treatment to a greater degree than others with the same or different symptoms of the condition.*  1. **Other**  * *Are there any other identified points of clinical exceptionality that do not fall into the above categories or that may not clinically relevant to this case? This includes, but not limited to, social and mental health factors which cannot be considered on their own.*  1. **Multiple Grounds**  * *Does this request require consideration on multiple grounds for the patient’s exceptional healthcare need?* |  | | | | |
| 1. **CLINICAL EFFECTIVENESS AND SAFETY** | | | | | |
| 1. **What alternative intervention / treatment would be offered to this patient if the requested intervention is not funded?**   **Would this alternative intervention / treatment also be offered to other patients with the same healthcare need?** | Choose an item.  Please provide details | | | | |
| 1. **Please provide a comparison of the risks and benefits of the requested intervention against standard treatment (if available)** |  | | | | |
| 1. **Is the drug licensed in the UK for the intended use?** | Choose an item.  *Please provide links / extracts of license* | | | | |
| 1. **What is the evidence base for the clinical and cost effectiveness and safety of the drug for this indication?** | *Full published data rather than abstracts must be submitted with the application. If non available please state reasons (e.g. unlicensed):* | | | | |
| 1. **What are the intended clinical outcomes and how will these be measured to assess treatment response?** | *Include where appropriate, the validated clinical tools to be used and any relevant disease activity scores.* | | | | |
| 1. **What stopping criteria are in place to decide when the treatment has become ineffective?** |  | | | | |
| 1. **Is it anticipated that the requested treated would need to be dose escalated / repeated in the future?** | Choose an item.  *If yes, please provide details* | | | | |
| 1. **BALANCING THE INDIVIDUAL NEED FOR CARE WITH THE NEEDS OF THE COMMUNITY** | | | | | |
| 1. **How often would you expect to request this drug for this condition for a given size of population?** | *(Please provide data from clinical practice in all relevant GM providers to support this and provide information from other specialist centres outside GM where available)* | | | | |
| 1. **If the drug were to be funded for this patient on an individual basis, would the decision set a precedent for any other requests?** | Choose an item.  *Please provide a rationale for this answer* | | | | |
| 1. **Is the requested intervention part of a current or planned national or international clinical trial or audit?** | Choose an item.  *If yes, please attach details (e.g. name of trial including name of the trial and its protocol).* | | | | |
| 1. **If this requested treatment was not funded, what would be the anticipated impact on future health and social care services?**   **How would this compare to the impact on health and social care services for a patient with a similar healthcare need but who has not received the requested treatment.** |  | | | | |
| 1. **AFFORDABILITY** | | | | | |
| 1. **What is the cost of the treatment and how does this compare with standard/alternative treatment (if applicable)?**   *Please ensure you include all attributable costs that are connected to providing the treatment e.g. drug administration / follow-up/monitoring / diagnostics* |  | | | | |
| 1. **What is the cost of on-going monitoring to determine treatment continuation?** | *Please also state if this is part would be part of standard practice or in addition to standard practice* | | | | |
| 1. **ADDITIONAL INFORMATION FOR CONTINUATION OF TREATMENTS ONLY**   **Please only complete this section of the form when the request is for continuation of funding for a drug that has been previously approved by the GM IFR Panel**  **All requests which are for continuation of treatment previously approved by the GM IFR Panel should be submitted in a timely manner to allow the request to be processed through the GM IFR decision making process.** | | | | |
| 1. **How was the previous course of treatment funded?**   *(Please include any funding approval letters / references were applicable)* | |  | | |
| 1. **When did treatment commence?**   **When is treatment due to stop (or when did it stop)?**  **Please also state if there have been any delays during the patient’s treatment (e.g. clinical availability or social factors)** | | Click or tap to enter a date.  Click or tap to enter a date. | | |
| 1. **What was the clinical outcome of treatment and what clinical measures were used to record this?** | |  | | |
| 1. **Is the observed response to this course of treatment inline with the anticipated response as stated in the original funding application?** | | Choose an item.  *Please provide details:* | | |
| 1. **What are the anticipated outcomes of the continued treatment which is being requested?** | |  | | |
| 1. **What are the short and long term care plans for this patient?** | |  | | |
| 1. **How has the patient’s clinical picture changed from when the previous application for funding was submitted to the present day?**   *Please provide as much detail as possible on the improvement or deterioration of the patient’s condition during the course of treatment* | |  | | |
| 1. **Has there been any clinically relevant changes to any GMMMG commissioning Statements or National Guidance for this patient’s condition / treatment since the previous funding application?**   **If there has been changes, have these been taken into account when requesting a continuation of treatment?** | | Choose an item.  *If yes, please provide details*    *Please provide a clinical rationale as to why they have or have not been considered if applicable?* | | |
| **DECLARATION OF INTERESTS** | | | | | |
| 1. **Clinicians are required to disclose all material facts as part of the process. Are there any other comments/considerations that are appropriate to bring to the attention of the IFR Team?** |  | | | | |
| **CONSENT** | | | | | |
| **I confirm that this IFR has been discussed in full with the patient. The patient is aware that they are consenting for the IFR Team to access confidential clinical information held by clinical staff involved with their care about them as a patient to enable full consideration of this funding request.** | **YES**  **NO**  **Please note without patient consent funding requests are unable to be reviewed. All personal information will be removed prior to the consideration by the IFR panel.**  **Signature of referring clinician:**       **Date:** Click or tap to enter a date. | | | | |
| **Decisions are routinely communicated to the named referring clinician stated in ‘contact details’ i.e. the clinician taking overall clinical responsibility for the requested treatment. If another healthcare professional for the purpose of patient care requires a copy of the decision outcome correspondence, e.g. senior Trust pharmacist this can be facilitated on provision of a valid secure email address.** | **Name:** | | | | |
| **Designation:** | | | | |
| **Secure (@nhs.net) email:** | | | | |

**Please send the fully completed form to the GM IFR Team via secure email:** [**gm.eur@nhs.net**](mailto:gm.eur@nhs.net%20)

**APPENDIX A**

### Evidence Proforma

|  |  |  |  |
| --- | --- | --- | --- |
| Please provide reference to the key evidence for clinical exceptionality, clinical effectiveness, good use of resources and safety of this procedure/treatment in each of the papers submitted as part of the evidence base relevant to this application. | | | |
| **No.** | **Title submitted**  **paper** | **Topics** | **Specific sections with key evidence (page number/paragraph or section)** |
| 1. | Article one | Clinical exceptionality |  |
| Clinical effectiveness |  |
| Good use of resources |  |
| Safety of this  procedure/treatment |  |
| 2. | Article two | Clinical exceptionality |  |
| Clinical effectiveness |  |
| Good use of resources |  |
| Safety of this  procedure/treatment |  |
| 3. | Article three | Clinical exceptionality |  |
| Clinical effectiveness |  |
| Good use of resources |  |
| Safety of this  procedure/treatment |  |
| 4. | Article four | Clinical exceptionality |  |
| Clinical effectiveness |  |
| Good use of resources |  |
| Safety of this  procedure/treatment |  |
| 5. | Article five | Clinical exceptionality |  |
| Clinical effectiveness |  |
| Good use of resources |  |
| Safety of this  procedure/treatment |  |
| 6. | Article six | Clinical exceptionality |  |
| Clinical effectiveness |  |
| Good use of resources |  |
| Safety of this  procedure/treatment |  |