**Regional Medicines Optimisation Committee (RMOC) Free of charge (FOC) medicines schemes guidance#**

*“A free of charge medicines scheme is defined as an arrangement where a UK licensed or unlicensed medicine is provided free of charge by the company to an individual patient or an identified cohort of patients.*”

(See Section 9 of the RMOC Free of charge (FOC) medicines schemes guidance for full list of definitions).

|  |  |  |
| --- | --- | --- |
| SECTION 1: Free of charge scheme principles to be considered by the Trust (complete checklist below)  Yes No | | |
| The FOC scheme must be for a medicine where there is an unmet clinical need. |  |  |
| There is equal access for all patients with the agreed indication in the trust or unit that has signed a contract for the scheme (or equivalent). |  |  |
| Where an established treatment pathway exists, the evidence for the proposed place in treatment should be submitted |  |  |
| There are clear expected outcomes from the use of this treatment. |  |  |
| Full informed consent should be documented according to local procedures for each patient who opts to use a medicine supplied through a FOC scheme, including characteristics of the medicine and how the scheme will operate, any restrictions on duration of treatment and implications on future NHS commissioned treatments. |  |  |
| FOC medicine scheme endorsed by the Trusts medicines management committee (MMC), or equivalent (enter date of approval). | Click here to enter a date. | |
| The FOC scheme written contract is available & signed copy (or equivalent e.g. email trail) to be submitted with form |  |  |
| There has been consideration of the local health economy impact of adopting the FOC scheme (e.g. implications on nursing, pharmacy capacity, extra supportive measures secondary to toxicity, tests, scans etc.) |  |  |
| The Trust is clear about funding responsibilities of the FOC Scheme once the NICE TA or local commissioning agreement has been decided, depending on whether the outcome is positive or negative (i.e. the exit strategy).*+* |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| SECTION 2: | | | | | |
| Trust Name: | | Click here to enter text. | | | |
| FOC medicine to be considered: | | Click here to enter text. | | | |
| Preparation (strength and formulation): | | Click here to enter text. | | | |
| Pharmaceutical company: | | Click here to enter text. | | | |
| UK license status: | | Click here to enter text. | | | |
| Indication for FOC medicine/criteria for use: | | Click here to enter text. | | | |
| Specialty/Clinical unit: | | Click here to enter text. | | | |
| Line in therapy and what this replaces (if applicable): | | Click here to enter text. | | | |
| Regimen details\* (i.e. dose, route, duration, frequency, number of anticipated cycles, usual place of administration): | | Click here to enter text. | | | |
| Trust activity – please detail number of attendances (outpatient, inpatient, follow-ups) required for the use of the drug: | | Click here to enter text. | | | |
| Estimated number of anticipated patients per financial year | | Click here to enter text. | | | |
| Has pharmaceutical company submitted to NICE? | | Yes  No | | | |
| If Yes, what is the estimated publication date? | |  | | | |
| Exit Strategy (Scenario 1):  Funding arrangements agreed with pharmaceutical company for existing patients if drug gains NICE approval | | Click here to enter text. | | | |
| Exit Strategy (Scenario 2):  Funding arrangements agreed with pharmaceutical company for existing patients if drug gains NICE approval but the patient does not fit the funding criteria | | Click here to enter text. | | | |
| Exit Strategy (Scenario 3):  Funding arrangements agreed with pharmaceutical company for existing patients if the drug does not gain marketing authorisation / NICE approval | | Click here to enter text. | | | |
| Any other information/supporting evidence (level of evidence, phase of trial, protocol etc.) | | Click here to enter text. | | | |
| SECTION 3: Implications for commissioner ( Trust to complete)  Yes No | | | | | |
| Additional attendances required? | |  |  | Click here to enter text. | |
| Delivery implications? e.g. HRG, block, cost & volume etc. | |  |  | Click here to enter text. | |
| Extra clinical tests or monitoring required? | |  |  | Click here to enter text. | |
| Any other implications (e.g. follow up ratios, treating adverse effects, administration, workforce): | |  |  | Click here to enter text. | |
|  | |  | | | |
| Requesting clinician: | | Click here to enter text. | | | |
| Name of person completing: | | Click here to enter text. | | | |
| Job title of person completing: | | Click here to enter text. | | | |
| Email: | | Click here to enter text. | | | |
| Date submitted to NHS England: | | Click here to enter a date. | | | |
| Date of anticipated first treatment: | | Click here to enter a date. | | | |
| Any Further Comments? | |  | | | |
| Any | | | | | |
| *SECTION 4: Internal NHS England Use* | | | | | |
| This meets RMOC approval criteria: | |  | | | |
| This does not meet RMOC criteria: | |  | | | |
| Reason: | Click here to enter text. | | | | |
| Signed by commissioner: |  | | | | Click here to enter a date. |