National Cancer Medicines Advisory Group (NCMAG) Programme

# **NCMAG Proposal Form**

**This is a ‘Once for Scotland’ proposal seeking support for routine use of a treatment in one of the following categories of cancer medicines:**

* Off-label uses of licensed cancer medicines (branded, generic or biosimilar):
* for an illness or patient population not specified within the marketing authorisation
* for administration by a different route, dose, frequency or duration
* On-label uses of licensed generic or biosimilar medicines, known as off-patent use. This category is anticipated to include medicines which are not recommended by SMC, however the patent has expired since SMC advice was published, with the medicine now available at lower cost and current cost-effectiveness is unknown.

**The programme will not consider:**

1. medicines without any marketing authorisation (unlicensed medicines) in the UK
2. situations where a marketing authorisation is likely to be sought for the proposed medicine in the off-label use within 24 months
3. In situations where a regulatory decision on marketing authorisation is pending for a comparator product, in the same off-label use as a proposal received by NCMAG, the suitability of the proposal for NCMAG review will be considered on a case by case basis
4. established off-label uses which have already become standard of care nationally
5. paediatric indications
6. treatments that do not impact on disease behaviour, for example analgesics for cancer pain
7. medicines and uses within SMC remit.
8. proposed uses not supported by at least one full research article published in a peer-reviewed journal

**Only one treatment regimen and population should be included in each proposal.**

**Please complete the following in relation to your proposal**

|  |  |  |  |
| --- | --- | --- | --- |
| **Off-label or off-patent use** | Choose an item. | | |
| **Likely improvement to patient outcomes** | Yes | No | |
| **Likely cost saving** | Yes | No | Unknown |
| **Demand on service capacity** | Increase | Decrease | Unknown |
| **Likely to reduce inequity of access** | Yes | No | Unknown |
| **I confirm this proposal is supported by at least one full research article published in a peer-reviewed journal** | Yes | No | |

# Submissions to NCMAG for changes to practice should be led by a tumour site team lead working in collaboration with consultant colleagues across NHSScotland. It is advised that applicants seek support from a senior cancer care pharmacist within their team, as a national representative of the specialist pharmacist group, to complete this form.

# **Please send the completed proposal form in the PDF format to the NCMAG team mailbox** [**his.ncmag@nhs.scot**](mailto:his.ncmag@nhs.scot)**.**

# The team can also be contacted at this email address if more information or assistance with completion of the form is required. **Discussion with the NCMAG team is advised to confirm potential proposals are within remit.**

# **NCMAG Proposal Form**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Details of applicant | | | | |
| Name: | Click or tap here to enter text. | | | |
| Designation: | Click or tap here to enter text. | | | |
| Email address: | Click or tap here to enter text. | | | |
| Contact number: | Click or tap here to enter text. | | | |
| Please identify a preferred method of contact: | Email | | Phone | MSTeams |
| On behalf of [tumour group]: | Click or tap here to enter text. | | | |
| On behalf of [health board/organisation] | Click or tap here to enter text. | | | |
| Name of national representative pharmacist in support (see guidance for further information): | Click or tap here to enter text. | | | |
| Pharmacist Email Address: | Click or tap here to enter text. | | | |
| Details of proposed individual medicine or regimen to be used | | | | |
| Medicine name(s): | Click or tap here to enter text. | | | |
| Brand (if applicable) and formulation: | Click or tap here to enter text. | | | |
| Current licensed indication(s): | Click or tap here to enter text. | | | |
| Proposed indication: | Click or tap here to enter text. | | | |
| Status of proposed indication:  Licensed off-patent or off-label use;   * If licensed use, state SMC status  (not recommended, use outside an SMC restriction or no current SMC advice), include SMC advice number where appropriate * If off-label use, are you aware if the medicine has been licensed for this use in another region, for example by the European Medicines Agency or US Food and Drug Administration? | Click or tap here to enter text. | | | |
| Route and dosing information for proposed use (indicate if fixed course or continuous and expected duration).  Does this match the regimen in the supporting clinical trial(s)? | Click or tap here to enter text. | | | |
| Peer support for proposed use | | | | |
| Please list any national or international clinical guidelines or consensus statements that support the proposed medicine and its use. | Click or tap here to enter text. | | | |
| Please list name, email address and Health Board of colleagues that have reviewed and support this proposal.  Please include at least one representative from WoSCAN, SCAN, and from each of the cancer centres in the NCA (if there are no specialist clinicians in this area for an NCA centre, please state). | Click or tap here to enter text. | | | |
| Please select one of the following options which best describes the views of specialist clinicians across NHS Scotland on the evidence supporting the medicine use in this proposal |  | All clinicians firmly support the use based on current understanding of the evidence | | |
|  | Clinician interpretation of the evidence varies, but all support a national review | | |
|  | Other, please describe below | | |
| Click or tap here to enter text. | | |
| I confirm that national consensus for submitting a proposal was agreed and evidence (i.e team call/email trail) can be provided on request | Yes  No | | | |
| Is this being discussed within the Scottish Cancer Network? | Yes  No | | | |
| Target Population | | | | |
| Define the eligible patient population: | Click or tap here to enter text. | | | |
| Specify the criteria for patient selection, for example this may be aligned with the inclusion and exclusion criteria for the supporting clinical trial: | Click or tap here to enter text. | | | |
| Treatment Pathway | | | | |
| Specify the position of the proposed treatment in relation to the overall treatment pathway**:** | Click or tap here to enter text. | | | |
| Outline how this proposed treatment will change the existing treatment pathway, for example does the proposal provide a new treatment line, replace or provide an additional option for a specified subpopulation | Click or tap here to enter text. | | | |
| Current standard of care (SOC) treatment options | | | | |
| * State current SOC for this indication * Please note if there is any variation between networks | Click or tap here to enter text. | | | |
| Are there any medicines expected to receive a marketing authorisation in this disease area that would address the clinical need being described here. Please include the name of the medicine and an estimate of marketing authorisation date if possible. | Click or tap here to enter text. | | | |
| Service implications | | | | |
| Describe the service requirements and indicate quantities if available for the current and proposed treatments. Consider the following and specify whether the estimates are at a local or national level to allow calculation:   * Is this a replacement or additional treatment? * Implications for bed occupancy/ capacity of day units/outpatients/primary care * Impact on medical, nursing and pharmacy staff (for example, more clinic appointments, longer infusion times, involvement of other medical specialties) * Any additional laboratory testing required, for example companion diagnostic or monitoring * Any additional radiology required * Specify where patients will be treated – cancer center/local cancer unit/outreach/primary care | Click or tap here to enter text. | | | |
| * How many patients are estimated to be eligible for the proposed medicine/regimen?   Please estimate the proportion of eligible patients who would likely receive this treatment nationally.   * How were these estimates derived? * Please state if estimates are at a national or local level | Click or tap here to enter text. | | | |
| Benefits and risks | | | | |
| State potential benefits to **i)** patient **ii)** service over current treatment | Click or tap here to enter text. | | | |
| State potential risks to **i)** patient **ii)** service over current treatment | Click or tap here to enter text. | | | |
| Evidence of favourable benefit-harm balance (clinical) | | | | |
| * Provide a brief summary of the published clinical trial evidence supporting the proposed medicine. Key points to address: study population, primary outcomes, comment if the study control arm is relevant to current practice, and safety profile. * The proposal must be supported by at least one full research article published in a peer-reviewed journal. An abstract is not considered an acceptable level of evidence. * Provide formal references in  item13*.* | Click or tap here to enter text. | | | |
| Are the study population and population described in section 4 of this form the same? If not, please describe the differences? | Click or tap here to enter text. | | | |
| Evidence of cost-effectiveness | | | | |
| Are you aware of any published (or soon to be published) cost-effectiveness evidence for the proposed medicine/regimen in this population? | Click or tap here to enter text. | | | |
| Patient and Carer Experience | | | | |
| Describe anticipated patient and/or carer benefits e.g. improved quality of life, prolonged independent living, delaying the need for more toxic treatments. | Click or tap here to enter text. | | | |
| Declaration of Interests | | | | |
| * Please refer to the following [DOI policy](https://www.healthcareimprovementscotland.org/previous_resources/policy_and_strategy/evidence_directorate_doi.aspx) and report below any DOI appropriate to the current proposal. * Please also report any relevant academic conflicts of interest | Click or tap here to enter text. | | | |
| Reference | | | | |
| Reference all evidence submitted. | Click or tap here to enter text. | | | |