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National Cancer Medicines Advisory Group (NCMAG) Programme

NCMAG Proposal Process Guidance

Version 8.0

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Introduction

The purpose of this document is to provide information to proposers on the processes for submission of proposals to NCMAG and what to expect once you have made a submission to NCMAG. For background information on the NCMAG programme, please visit our webpages.

Section 1: How to check a proposal meets NCMAG Proposal Criteria

1.1 NCMAG Council make decisions on proposals which apply to groups of patients.

The Programme appraises and issues advice on medicines uses in the following categories which are out with the remit of Scottish Medicines Consortium (SMC):

- 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 or frequency
- On-label uses of licensed generic or biosimilar medicines, known as off-patent use. This category includes medicines which are not recommended by SMC, where the patent has expired since SMC advice was published, and the medicine is now available at a lower cost, so current cost-effectiveness is unknown.

1.2 Outwith remit criteria:

a) medicines without any marketing authorisation (unlicensed medicines) in the UK
b) situations where a marketing authorisation is likely to be sought for the proposed medicine in the off-label use within 24 months
c) 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
d) established off-label uses which have already become standard of care nationally
e) paediatric indications
f) treatments that do not impact on disease behaviour, for example analgesics for cancer pain
g) cancer medicines uses within SMC remit
h) proposed uses not supported by at least one full research article published in a peer-reviewed journal.

1.3 Remit check and process

Prior to submitting a full proposal, it is recommended that clinicians complete a remit check to establish whether the proposal meets the NCMAG criteria. The Remit check rquest form and details can be found here. Completed forms can be emailed to the NCMAG mailbox: his.ncmag@nhs.scot**.**

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Section 2: Process for submission of a proposal

2.1 Who can submit a proposal?

Submissions to NCMAG should be led by a tumour group specialist or consultant working in collaboration with specialist consultant colleagues across all NHSScotland cancer centres where the relevant patient population is treated. The nominated lead will submit the proposal for consideration.

Pharmacist input and support is required to work up proposal submissions. The pharmacist should be a tumour group specialist and act as the national pharmacist representative for the proposal, working in collaboration with peer tumour network and clinical pharmacist specialists from across all cancer centres.

2.2 What does submitting a proposal entail?

- Completion of a proposal form with key information for NCMAG Council consideration.
- Being the key contact for any additional questions the NCMAG team may have regarding the proposal. This may include provision of clinical expert review of NHSScotland real-world data.
- Presentation of the proposal at an NCMAG Council meeting. During the meeting, the lead proposer (or nominated deputy) will deliver the presentation and respond to any questions from Council members. To support the presenter, a briefing meeting with NCMAG will be held prior to the Council meeting.

2.3 Prior to submission check your proposal against the following criteria:

- Please ensure that your proposal contains only one line of treatment or patient group, for example, if the proposal is for use in the first and second line then these should be submitted as separate proposals as they will have different clinical evidence to support their use and the health economics will be different for each.
- The medicine meets off-label or off-patent criteria defined above.
- The proposal is supported by at least **one full research article published in a peer-reviewed journal**. An abstract is not considered an acceptable level of evidence.
- There is evidence of national consensus, with support for NCMAG review from all cancer centres treating the patient population. The submitting clinician is required to provide contact details of the supporting clinicians. This will allow the supporting clinicians to be sent an acknowledgement email on receipt of the proposal form and to allow the NCMAG team to ensure they are included in any relevant communications about the proposal.

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Section 3: Key considerations when completing the form

Note: This section provides further detail on key points for completing the form. If you require additional information, please contact the NCMAG team

3.1 Eligible Population and Estimated patient Numbers (see section 4 of proposal form)

- Carefully consider the patient population for the proposed use. This ensures that the evidence used in the assessment accurately reflects the intended use.
- **Eligible Population:**
  This section should describe the treatment and define any specific inclusion and exclusion criteria that apply. For example, specify the line of therapy, prior treatments, disease stage, and any relevant cancer genotypes. If these criteria differ from those used in the clinical trials supporting the treatment, please explain how they differ and why.
- **Uptake Population:**
  This refers to the population that will actually receive the treatment. Estimate the proportion (%) of the overall eligible patient population who are likely to receive this treatment. This is usually lower than the eligible population due to a range of factors including:
  - Performance status
  - Comorbidities
  - Specific contraindications
  - Alternative treatment options or patient preferences

  Please do not consider service capacity impact when making this estimate.
- **Patient Numbers**

If there are any uncertainties regarding patient numbers, please highlight them in the proposal form. If you are unable to access information to estimate patient numbers, please discuss with us. Estimates should not take account of potential service capacity limitations.

3.2 Current treatment options and pathway (see section 5 of proposal form)

- This section focuses on treatments routinely accessible for the specifically proposed eligible patient population.
  Please assume that the proposed treatment is not available and indicate what treatment would be given in its absence. These are the treatments that, if supported, the proposed treatment will displace or replace and will therefore be compared with.
- Treatments accessed through individual patient requests are not classed as routinely accessible and are therefore not usually considered in cost effectiveness considerations for health technology assessment. However, if they are accessed regularly in some centres, please provide this information as it will support understanding of treatments currently used in NHSScotland.
- If no treatments are currently routinely accessible, please state this.

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3.3 Treatment Pathway

- Please outline the anticipated impact of the proposed use in the treatment pathway, relative to existing routinely accessible treatments – detail what treatments would be removed or moved to a different place in the pathway. This information is important for cost-effectiveness analysis and budget impact assessment.

If possible, for each current standard of care regimen, please estimate:

- The *current* share of use (%) for each treatment currently used,

AND

- The *expected* share of use (%) of each current treatment if the proposed treatment(s) is/are supported. This may be difficult to predict definitively, but please provide the best possible estimate.

If required, **additional rows** may be added to the relevant table in the proposal form.

3.4 Clinical Evidence Requirements (see section 8 of proposal form)

In terms of evidence for the proposed treatment, reference to a minimum of one full research article published in a peer-reviewed journal is required; however, there is no need to list or summarise all available literature, as the NCMAG team will conduct a systematic literature review.

If you have any questions about completing the form, please feel free to contact the NCMAG team.

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Section 4: Submitting your proposal and what happens next

How should a proposal form and supporting documents be submitted?

- The nominated lead will submit the proposal via email to the NCMAG mailbox: **his.ncmag@nhs.scot**.
- In addition to this document, further advice on the process/proposal prior to submission can be sought via the NCMAG email address.
- The NCMAG team may be in contact with the nominated lead to request further information in advance of the screening and prioritisation step or in advance of consideration at the NCMAG Council.
- Council meetings to review proposals are held quarterly in March, June, September and December.
- There are set submission deadlines for proposals which fall in January, April, July and October – exact dates can be found **here**.
- Proposers will be notified via email confirming the date of the NCMAG council meeting at which their proposal will be considered.

4.1 Screening and prioritisation

- Once a proposal is received, it will be reviewed against pre-determined criteria by the NCMAG Programme Team to assess suitability for consideration by the NCMAG Council.
- The proposer will be notified via email confirming if the proposal has or has not been considered within remit.
- Depending on the volume of proposals received, it may be necessary to prioritise review and scheduling. Prioritisation will follow pre-determined criteria and be conducted by the NCMAG Executive.

4.2 Prior to the meeting

- For proposals considered appropriate for consideration by the Council, the NCMAG team will confirm the meeting date to the proposer.
- Proposals suitable for consideration by the NCMAG Council will go through an internal evidence review process, including a systematic literature review, appraisal and quality assessment of the evidence relevant to the proposal.
- NCMAG team may collaborate with groups, including the Cancer Medicines Outcome Programme and Public Health Scotland (CMOP-PHS), to provide data to support NCMAG review of the proposal. Please note that proposers and the listed supporting clinicians' names and contact information will be shared with the CMOP-PHS team. The CMOP-PHS team may be in contact regarding the data obtained from the National Systemic Anticancer Therapy (SACT) dataset in relation to the NCMAG proposal, for the purpose of data quality assurance.
- The proposer may be asked to provide additional information prior to the meeting to support

the review.

- Ahead of the meeting the proposer will be issued with a presentation template to support contribution at the council meeting. If the proposer is unable to attend, we would request the proposer nominates a deputy, ideally from the co-proposer(s) who would be able to present on their behalf.
- The NCMAG team will liaise with National Procurement to consider matters related to procurement and supply of the proposed medicine, where relevant.
- The NCMAG team will invite relevant Patient Group organisations to identify and consider the perspective of patients and carers in relation to the proposal. Patient Group Partners (PGPs) who engage with NCMAG will provide statements in advance of the meeting which will be shared with council members.

4.3 At the meeting

- The NCMAG Council includes a wide range of stakeholder representatives, who will consider proposals.
- The proposer or deputy is invited to join the NCMAG council meeting to provide a brief presentation of the clinical context and case for the proposal as well as responding to any questions from council members.
- The NCMAG team will present the results of the internal review of clinical and economic evidence specific to the proposal. The NCMAG team will also present a summary of the statements provided by the PGPs.
- The NCMAG Council members are invited to ask any questions of the proposer, PGPs and NCMAG team.
- The proposer is asked to leave the meeting prior to the NCMAG Council members reaching their decision on whether the proposal is supported or not supported.
- Decisions are based on the information provided to council members in advance and on the day of the meeting.

4.4 After the meeting

- The NCMAG team will finalise the advice document, taking into consideration the discussion and decision made by the Council.
- One week after the meeting, the advice document is shared in confidence with the proposer and health boards.
- Four weeks after the meeting, the NCMAG council decision is shared in confidence with the relevant patient group partner(s).
- Five weeks after the meeting, the final advice document will be issued to Health boards and Regional Cancer Networks and published on the public facing NCMAG Programme webpage.
- Implementation of NCMAG supported advice is subject to Boards' usual medicines governance processes. All cancer networks and Boards are expected to facilitate access to

medicines supported by the group.

- SACT Protocol:
    - NCMAG aims to support the sharing of draft SACT protocols, and to ensure consistent naming of supported proposals across all instances of Chemocare.
    - If the proposal is supported, the proposer will be encouraged/ requested to work with the pharmacist named on the proposal to develop a draft SACT protocol, to help avoid duplication of effort producing protocols regionally. The drafting team is asked to share this with co-proposers and team pharmacists (copying in NCMAG), to share with relevant regional network and board contacts for consideration through regional governance processes: local adaptations may be required.
    - We recognise that in some instances there may already be SACT protocols in place across Scotland for the supported indication. In which case we request the proposer liaises with co-proposers to agree that current protocols are updated to include the NCMAG supported indications with appropriate wording for patient selection criteria and dosing, in line with the NCMAG advice document wording.

4.5 Will advice be reviewed after publication?

Advice may be reviewed or resubmission considered, when significant new clinical information is highlighted by clinical groups.