National Cancer Medicines Advisory Group (NCMAG) Programme

NCMAG Proposal Form Guidance

Version 7.0

Visit NCMAG Programme Webpage for more information

Background

The purpose of the NCMAG Programme is to provide advice on the safe implementation of new uses of cancer medicines where a "Once for Scotland" approach would be of benefit to improve consistency, equity of access, avoid duplication and support recovery from the pandemic. This would include medicines 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 and
- On-label uses of licensed generic or biosimilar medicines, known as off-patent use

The programme is intended to work alongside SMC and existing local systems to support access to cancer medicines. The work programme is driven by clinical need in consultation with Scottish Government Health Department (SGHD) Pharmacy and Medicines Division and Cancer Policy Teams, National Cancer Recovery Group, and stakeholders across NHSScotland.

Decisions on treatment need to be made on an individual patient basis by clinicians in discussion with the patient and, where appropriate, the multidisciplinary team. NCMAG Council will make decisions on proposals which will apply to groups of patients, notwithstanding that individual documented patient assessment and discussions will still be required.

Proposals to the group

The Programme will appraise and issue advice on the off-label and off-patent use of cancer medicines, including:

- 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 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:

- medicines without any marketing authorisation (unlicensed medicines) in the UK
- situations where a marketing authorisation is likely to be sought for the proposed medicine in the off-label use within 24 months
- 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
- established off-label uses which have already become standard of care nationally
- paediatric indications

- treatments that do not impact on disease behaviour, for example analgesics for cancer pain
- medicines and uses within SMC remit
- proposed uses not supported by at least one full research article published in a peer-reviewed

Process

Who can make a proposal?

Individual consultants wishing to implement a change should initially seek support from specialist colleagues within their team/Managed Clinical Network and from specialist colleagues across Scotland. Submissions to NCMAG for changes to practice should be led by a tumour site specialist working in collaboration with specialist consultant colleagues across NHSScotland. The nominated lead will submit the proposal for consideration.

Pharmacy input and support should be sought to work up proposal submissions. The national pharmacist representative should be a tumour network lead working in collaboration with peer tumour network and clinical pharmacist leads. Contact details are available via the SOPPG MS teams channel.

What does the proposal entail?

It requires the completion of a proposal form with key information which will support the NCMAG Council to appraise the evidence and decide whether to support the routine use of the proposed treatment.

It is important that prior to submission you check your proposal against the following criteria:

- Please ensure that your proposal contains only one treatment/ patient group.
- 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 from all three cancer networks. The submitting clinician is required to provide contact details of the supporting applicants included in the proposal. This will allow the supporting applicants to be sent an acknowledgement email on receipt of the proposal form.
- Clearly defined eligible patient population for whom the proposed use is intended.

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 will be held at least every 3 months and, depending on demand, possibly more frequently.
- Proposers are required to submit proposals by set submission deadlines which can be found **here**.

- The aim is for proposals to be scheduled for review within 4 months of receipt of submission. Proposers will be notified via email confirming the date of the NCMAG Council meeting at which their proposal will be considered.

What happens to submitted proposals?

Screening and prioritisation

- Once a proposal is received it will be reviewed against pre-determined criteria by the NCMAG Programme Team to assess its suitability for consideration by the NCMAG Council.
- The proposer will be notified via email confirming if the proposal has or has not been considered appropriate for review.
- In the event that the proposal is likely to have a significant service implication, we may require additional input from service managers to explore this further.

  Depending on the volume of workload, there may be a need to prioritise proposals received. Prioritisation will follow pre-determined criteria and be conducted by the NCMAG Executive.

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 may be shared with the CMOP-PHS team. The CMOP-PHS team may be in contact regarding the data obtained from the national 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 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.

At the meeting

- The NCMAG Council includes a wide range of stakeholder representatives, who will consider proposals at the meeting.
- The proposer or a deputy is invited to join the NCMAG council meeting to provide a brief presentation on the proposal, using the template provided in advance.
- The NCMAG team will present the results of the internal clinical and economic evidence review. 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 to allow the NCMAG Council members to make a decision on whether the proposal will be supported or not supported by NCMAG.
- Decisions are based on the best available information provided on the day of the meeting.

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 with the proposer in confidence for comment on accuracy only.
- The final advice document will be issued to Health boards and Regional Cancer Networks and added to the NCMAG Programme webpage. Boards will still need to consider local governance issues and the service/budget impact of changes. 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 SACT protocols, and to ensure consistent naming of supported proposals across all instances of Chemocare.
    - If the proposal is supported, the proposer will be requested to work with the pharmacist named on the proposal to develop a SACT protocol for sharing, to help avoid duplication of effort producing protocols regionally.
    - The SACT protocol will be shared 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 will 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.

How long will the advice be valid?

All advice will be reviewed every three years, or when new information or evidence becomes available. Reviews may result in advice being extended, changed or withdrawn.