National Cancer Medicines Advisory Group (NCMAG) Programme

Health economic considerations in NCMAG decision making

October 2023 | Version 1.0

Healthcare Improvement Scotland

Contents

1. Introduction

The aim of the NCMAG programme is to deliver advice which supports equitable access to safe and effective off-label and off-patent uses of cancer medicines to improve outcomes for cancer patients across NHSScotland. The programme provides a more efficient, systematic 'once for Scotland' approach to facilitate rapid and effective implementation of off-label and off-patent use of cancer medicines into routine practice and help minimise unwarranted variation.

Newly licensed medicines are submitted by pharmaceutical companies to national bodies for health technology assessment (HTA). When a medicine achieves better health outcomes and is more costly than the medicine it will replace, complex cost-effectiveness models, including quality of life data and costs, are used to demonstrate value for money. Pharmaceutical companies invest substantial financial and time resource into developing these models for HTA review. Academic groups may also include cost utility models in clinical trial plans.

As per NCMAG guiding principles the work programme is driven by clinical need with proposals submitted by clinicians. As decision making based on cost effectiveness is preferred, the NCMAG team conduct systematic literature searches and contact pharmaceutical companies and/or academic groups to explore different avenues to obtain cost-effectiveness analyses. However, if none is available, the NCMAG team do not have capacity to undertake this type of analysis themselves.

The role of NCMAG council is to make decisions on the proposals following careful consideration of all relevant information. Where a cost-effectiveness analysis is available to support decision making on a proposal, Council members refer to the NCMAG position on the Incremental cost-effectiveness ratio (ICER) range, described in Section 2. Where there is an absence of cost-effectiveness information Council members refer to the NCMAG Decision-making framework for value judgements, described in Section 3.

2. NCMAG Position on the Incremental Cost-effectiveness Ratio Range

This section sets out the NCMAG position on the ICER range for informing decision making.

2.1 Background

The incremental cost-effectiveness ratio is often calculated as net cost per quality adjusted life year (QALY) gained, providing a summary figure for cost-effectiveness. Its advantages are that it is a single figure and allows comparison with other healthcare interventions. However, the reporting of an ICER alone is not sufficient. To decide whether the benefits of an intervention are sufficient to justify the costs also depends on the value of what is given up as a consequence, that is, the opportunity costs. To establish whether an intervention that imposes additional costs represents a 'cost-effective' use of resources requires some comparison with the opportunity costs. Hence, to determine if an intervention is 'cost-effective', requires consideration of a threshold range. The use of a threshold range allows for a comparative framing of the generated ICER.

The origin and use of ICERs is a thought-provoking area within Health Economics. Although authors strive to obtain a scientifically derived cost-effectiveness ICER threshold, it is an area that remains open to debate [4-8].

2.2 Use of ICER ranges in decision making

The position of NCMAG on the use of ICERs to inform decision making seeks to be consistent with other groups that consider the cost-effectiveness of health interventions, including Scottish Medicines Consortium (SMC)[1], Scottish Health Technologies Group (SHTG) and The National Institute for Health and Care Excellence (NICE)[2]. As a result, NCMAG notes the following NICE guidance:

- Below a most plausible ICER of £20,000 per QALY gained, the decision to recommend a technology is normally based on the cost-effectiveness estimate and the acceptability of a technology as an effective use of NHS resources. When the estimated ICERs are less than £20,000 per QALY gained, and it is decided that the technology should not be recommended, specific reference will be made to the uncertainty in the estimated ICER and/or plausibility of the inputs to the economic model.
- As the ICER for a technology increases in the range of £20,000 to £30,000 per QALY gained, the decision about the acceptability of the technology as an effective use of NHS resources will make explicit reference to: the degree of certainty and uncertainty around the ICER; aspects that relate to uncaptured benefits and non-health factors.
- Above a most plausible ICER of £30,000 per QALY gained, an increasingly stronger case for supporting the technology as an effective use of NHS resources will be

required. This will make explicit reference to: the degree of certainty and uncertainty around the ICER; aspects that relate to uncaptured benefits and non-health factors.

- For technologies that provide less health benefit at a lower cost compared with the relevant comparator(s), cost-effectiveness considerations should consider the usual cost-effectiveness levels of £20,000 to £30,000 per QALY. Aspects that relate to uncaptured benefits and non-health factors should also be considered. Consistent with the guiding principles of NCMAG, it is not anticipated that this case will be reviewed.

In alignment with SMC [1] and NICE[2], NCMAG does not have a defined maximum ICER above which an intervention would automatically be defined as not cost-effective or below which it would automatically be considered cost-effective.

2.3 Uncaptured benefits and non-health factors

As the ICER increases beyond £20,000 per QALY gained, consideration of uncaptured benefits and non-health factors may be referred to in the decision-making process. These may include, but are not limited to, the following examples:

- When there is reason to support the view that health benefits are inadequately captured and the health utility gained is misrepresented
- Evidence of substantial improvement in life expectancy (with sufficient quality of life)
- Evidence of substantial improvement in quality of life
- Evidence that a specific subgroup of patients may benefit
- Absence of other therapeutic options of proven benefit provided in NHS Scotland

These examples seek to be in alignment with NICE guidance[2] and SMC guidance on decision modifiers[3]. Any additional factors may be considered in accordance with the application of the guiding principles of NCMAG.

3. NCMAG Decision-making framework for value judgements

This decision-making framework includes an approach to proposals with compelling clinical cases where there is an absence of cost-effectiveness information. Service impact and budget impact information may be considered as part of the value judgement deliberations.

The aim of the framework is to provide a robust process to support consistent application of principles while allowing appropriate flexibility for decision-makers to consider specific proposals. In doing so, the framework provides a more efficient, systematic 'once for Scotland' approach to facilitate effective implementation of off-label and off-patent use of cancer medicines into routine practice and help minimise unwarranted variation.

3.1 Need for a decision-making framework for value judgements

Newly licensed medicines are submitted by pharmaceutical companies to national bodies for Health Technology assessment (HTA). When a medicine achieves better health outcomes and is more costly than the medicine it will replace, pharmaceutical companies or academic groups invest substantial resource into developing complex cost-effectiveness models, including quality of life data and costs, which are used to demonstrate value for money.

NCMAG proposals come from groups of clinicians and do not include cost-effectiveness analyses. The NCMAG team conduct systematic literature searches and contact pharmaceutical companies and/or academic groups to explore different avenues to obtain cost-effectiveness analyses. However, if none is available, the NCMAG team do not have capacity to undertake this type of analysis themselves.

Prior to this update, there was no national decision-making framework for off-label proposals with a strong clinical case but with no cost-effectiveness analysis. Individual requests have been submitted by clinicians to local/regional medicines groups for review, taking considerable clinician time. In the absence of national guidance on decision making for these reviews, the individual review process has been variable in robustness and transparency, resulting in national inefficiency and unequal access to medicines across Scotland.

The framework supports NCMAG review of a range of proposals and provides a mechanism for standardised 'Once for Scotland' decision making. The benefits of this include equitable access to cancer medicines across Scotland, improved patient outcomes, reduced inefficiency, and strengthening of governance, transparency and consistency.

3.2 Elements of approach to value judgements

3.2.1 Absence of cost-effectiveness information

For proposals associated with greater clinical benefit and greater costs than the relevant comparators, the NCMAG team will source, assess and review all available information, including findings of systematic literature review and cost comparison analysis. In the absence of an appropriate cost-effectiveness analysis, information on the strength of the

clinical case; medicine, administration and monitoring costs on a per patient basis; service impact; net medicines budget impact; and statements on uncaptured benefits from patient groups will be included to help inform a value judgement.

3.2.2 Compelling clinical case

Where there is absence of an appropriate cost-effectiveness analysis, consideration of key factors reflecting clinical impact will be referred to in the decision-making process. These may include, but are not limited to, the following examples:

- Evidence of substantial improvement in life expectancy (with sufficient quality of life)
- Evidence of substantial improvement in quality of life
- Evidence that a specific subgroup of patients may benefit
- Absence of other therapeutic options of proven benefit provided in NHS Scotland

The Council will make a judgement on whether a clinical case is compelling or not. Validated tools, such as the European Society of Medical Oncology magnitude of clinical benefit scale, may be used to support this consideration.

Unintended consequences, including risk of introducing inequality, and any additional factors, may be considered in accordance with the application of NCMAG guiding principles.

3.2.3 Uncaptured benefits and non-health factors

Like decision-making when there is a cost-effectiveness analysis, uncaptured benefits and non-health factors are explored through the contribution of patient groups.

3.2.4 Cost comparison

The framework has a cost-comparison analysis which includes medicine and associated costs, such as administration and monitoring, on a per patient basis for the proposed regimen and the regimen it is anticipated to replace.

3.2.5 Considering the budget and service impact of a proposal

A detailed net national medicines budget impact analysis, which includes a greater level of detail than when a cost-effectiveness analysis is available, is considered by Council.

There is no quantitative threshold for considering service impact in NHSScotland. Contributions from relevant stakeholders will inform discussions at Council on whether a proposal is likely to be associated with a high service impact.

3.2.6 Reconsideration of published advice in light of new information

If meaningful new information relating to the key elements of the value judgement framework becomes available to the NCMAG team following the Council decision and publication of advice, the NCMAG Executive team will be consulted on whether the advice should be reconsidered through NCMAG Council or otherwise.

References

1. Healthcare Improvement Scotland Scottish Medicines Consortium: Guidance to submitting companies for completion of New Product Assessment Form (NPAF) [Internet]; [posted 2021 Sep; cited 2022 Feb 23]. Available from: Making a submission (scottishmedicines.org.uk)
2. National Institute for Health and Care Excellence: NICE health technology evaluations: the manual [Internet]; [posted 2022 Jan 31; cited 2022 Feb 23]. Available from: Introduction to health technology evaluation | NICE health technology evaluations: the manual | Guidance | NICE
3. Healthcare Improvement Scotland Scottish Medicines Consortium: SMC modifiers used in appraising new medicines [Internet]; [posted 2012 June; cited 2022 March 09]. Available from: Policies & publications (scottishmedicines.org.uk)
4. McCabe C, Claxton K, Culyer AJ. The NICE cost-effectiveness threshold: what it is and what that means. Pharmacoeconomics. 2008;26(9):733-44.
5. University of York Centre for Health Economics: Methods for estimation of the NICE cost-effectiveness threshold [Internet]; [cited 2022 March 09]. Available from: https://www.york.ac.uk/che/research/teehta/thresholds/
6. Claxton K, Martin S, Soares M, Rice N, Spackman E, Hinde S, Devlin N, Smith PC, Sculpher M. Methods for the estimation of the National Institute for Health and Care Excellence cost-effectiveness threshold. Health Technol Assess. 2015 Feb;19(14):1-503.
7. Raftery J. Should NICE's threshold range for cost per QALY be raised? No. BMJ. 2009 Jan 26;338:b185
8. Towse A. Should NICE's threshold range for cost per QALY be raised? Yes. BMJ. 2009 Jan 26;338:b181.
9. Cherny NI, Dafni U, Bogaerts J, Latino NJ, Pentheroudakis G, Douillard JY, *et al.* ESMO-Magnitude of Clinical Benefit Scale version 1.1. Annals of Oncology. 2017;28(10):2340-66.