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Evaluation of National Cancer Medicines Advisory
Group programme impact – Case study on prescribing
patterns before and after NCMAG advice

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Introduction

The National Cancer Medicines Advisory Group (NCMAG) Programme provides advice to territorial NHS Boards on the clinical and cost-effectiveness of clinician-proposed cancer medicine uses, that are off patent or off label and outside Scottish Medicines Consortium (SMC) remit.

The programme has been issuing advice since June 2022.

Cancer treatment can be high cost and high risk and is therefore robustly governed and highly protocolised. Worldwide estimates are that 40 to 50% of cancer treatment protocols include medicines which are used outwith their licensed indication (“off-label medicine uses”). The pharmaceutical industry cannot promote off-label uses of medicines and often choose not to extend product licenses to incorporate new uses, particularly when patient populations are small, or medicines are nearing the end of their patent and protected exclusive manufacturing.

Prior to NCMAG there was no forum for national review of evidence supporting off-label uses of cancer medicines or mechanism to revisit on-label uses of medicines which had become off patent with cheaper generic or biosimilar alternatives available. The consequences of this were duplication of local decision-making processes and variance in access for patients resulting in postcode prescribing, staff resource wastage and lost opportunity to improve patient outcomes. NHS Boards are responsible for governance of all medicines, supported by national “Once for Scotland” programmes which support efficiency and reduce the risk of variation. The NCMAG programme aligns with Scottish Government cancer policies to embed a process for national review of off-label and off-patent cancer medicine uses in Scotland. The programme works alongside SMC and existing local systems for access to cancer medicines.

Key aims of the NCMAG programme are to deliver advice on clinically relevant, clinician-submitted proposals, which support equitable access to uses of cancer medicines, improve process efficiency and improve outcomes for patients across NHSScotland. Data on the impact of NCMAG advice on patient outcomes are not available; however, data on some important indicators of impact are available. These include information on a case study on the prescribing pattern before and after NCMAG advice.

Background

Several tyrosine kinase inhibitors (TKIs) are licensed (on-label) and accepted for use in the first-line treatment of advanced renal cell carcinoma (RCC). Immunotherapy with ipilimumab and nivolumab was subsequently accepted as an alternative first-line treatment, but no medicines were licensed for use in patients whose cancer progressed after this treatment (second-line use). In the absence of licensed options for second-line treatment, clinicians and patients were either cautious about choosing first-line doublet immunotherapy or submitted individual patient requests to use an off-label TKI on progression, with variation in access across NHSScotland. NCMAG issued advice for the second-line treatment of

advanced RCC following first-line combination immunotherapy in January 2024. Two TKI medicines were proposed and reviewed, with sunitinib (NCMAG 111) supported and pazopanib (NCMAG 112) not supported (Table 1). This case study explores prescribing practices for the second-line treatment of advanced RCC before and after NCMAG advice was issued.

Table 1 | NCMAG advice relevant for case study

Shared with Boards	Medicine	Use	Decision	Advice summary
January 2024	Sunitinib	Second line treatment of adult patients with poor or intermediate risk advanced/metastatic RCC who have received nivolumab in combination with ipilimumab as first line treatment. (Off-patent use).	Supported	NCMAG111
January 2024	Pazopanib	Second line treatment of adult patients with poor or intermediate risk advanced/metastatic RCC who have received nivolumab in combination with ipilimumab as first line treatment. (Off-label use).	Not supported	NCMAG112

Method

The Cancer Medicines Outcome Programme – Public Health Scotland (CMOP-PHS) draws on data from national datasets to provide deeper insight into patients' treatments. This study, exploring prescribing patterns before and after issue of NCMAG decisions on Proposals 111 and 112, is based on data provided by CMOP-PHS. This is considered an observational before-and-after analysis and does not attempt to attribute a direct cause-and-effect relationship.

The study included patients from a sub-population treated for advanced RCC:

- following prior treatment with ipilimumab plus nivolumab (assumed to be their first-line treatment for intermediate or poor risk advanced RCC)
- treated with a medicine from a class called TKIs (including sunitinib and pazopanib)
- treated between 1 July 2022 and 30 June 2025. This covers approximately 18 months before and 18 months after issue of advice NCMAG111 and NCMAG112.

The following were excluded: patients younger than 18 years old at start of treatment and those receiving TKIs as part of a clinical trial.

Results

Impact on volume and profile of TKI prescribing

Twenty-six patients were identified as those who had received first-line nivolumab plus ipilimumab and second-line TKI for treatment of presumed advanced or metastatic RCC. Of the 26 patients, 8 commenced treatment in the 18 months prior to January 2024 and 18 in the 18 months from January 2024. This shows an increase in use by 10 patients or 125% (8 to 18).

Of the TKIs prescribed, sunitinib use went from 12.5% (1 of 8) to 72% (13 of 18) and use of other TKIs went from 87.5% (7 of 8) to 28% (5 of 18). As sunitinib was the only off-patent option, these proportions also reflect the increased use of a lower-cost medicine. Full details are presented in Table 2.

Table 2| Profile of tyrosine kinase inhibitor use 18 months before and after issue of NCMAG advice

		All (N = 26)	PRE 2024 (N = 8)	POST 2024 (N = 18)
Second line TKI	Sunitinib	14 (53.8%)	1 (12.5%)	13 (72.2%)
	Pazopanib	4 (15.4%)	4 (50.0%)	0 (0.0%)
	Other TKI ^a	8 (30.8%)	3 (37.5%)	5 (27.8%)

^a this includes axitinib (plus pembrolizumab), cabozantinib and tivozanib. TKI = tyrosine kinase inhibitor

Impact on regional distribution of prescribing

Access to a TKI in this setting prior to January 2024 was through individual patent request processes. The distribution of patients receiving access to a TKI across the regional cancer networks was not proportionate to their populations, with no access reported in one region. In the 18-month period following NCMAG advice, there was access seen across all regions with regional distribution of patients accessing TKIs being broadly proportionate to the size of populations.

Impact on use of first-line nivolumab in combination with ipilimumab

There was an increase in the use of nivolumab plus ipilimumab for first-line treatment of advanced or metastatic RCC following dissemination of the NCMAG decision with an increase

from approximately 30 patients to approximately 40 patients – representing an approximate 33% (10 patients) increase.

Discussion

Key aims of the NCMAG programme are to deliver advice which supports equitable access to safe and effective off-label and off-patent uses of cancer medicines and improve process efficiency. The reported data show a change from inconsistent and disproportionate use of TKIs across the three regional cancer networks prior to NCMAG advice, to an approximately proportionate distribution of use in the period following NCMAG advice. The period for analysis was limited (18 months before and after issue of NCMAG advice) and the number of patients in the sample was small (n=26), which may limit the generalisability of findings; however, the results are encouraging and suggest that NCMAG advice supports equitable access to medicines across NHSScotland and limits postcode prescribing.

The clinical relevance of NCMAG advice is demonstrated by the 125% increase (8 to 18) in patients receiving TKIs after progression on combination immunotherapy, with the increase being entirely driven by the increased use of sunitinib. The data highlights an increase in use of first-line nivolumab plus ipilimumab, the only first-line immunotherapy combination option. Proposing clinicians highlighted that use of this effective first-line combination had previously been limited due to uncertainty about access to a second-line TKI option if patients' cancer progressed. NCMAG advice has addressed this challenge in the treatment pathway by providing a routinely accessible second-line option and may have supported increased use of the effective first-line immunotherapy combination option.

At the time of NCMAG review in December 2023, sunitinib was the lowest cost TKI used in renal cell carcinoma as it was off patent with generic versions available for use in NHSScotland. The report highlights that since NCMAG 111 and NCMAG 112 advice there has been an increase in access to TKI medicines in this setting, an increase in use of the lowest cost TKI option, and reduced need for individual patient requests and their associated administrative burden. These figures indicate that NCMAG advice is likely to be associated with improved resource use through cost-effective prescribing and process efficiency.

Conclusion

The data reported in the case study on prescribing patterns indicates that NCMAG advice in this area is clinically relevant and supports equity of access to medicines and cost-effective use of resources across NHSScotland. It provides supportive evidence of impact, complementing the wider implementation findings.

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