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WHAT IS THE RECOMMENDED LEVEL OF PATIENT ACCESS?

An Analysis of NICE's Optimised Decisions from 2015 to 2024

CONTRACT RESEARCH REPORT
MAY 2025

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Please cite this report as:
Darrow B., Chowdhury S., O'Neill P., Henderson N., 2025. An Analysis of 10 Years of NICE Optimised Decisions: What is the Recommended Level of Patient Access? OHE Contract Research Report, London: Office of Health Economics. Available at: https://www.ohe.org/publications/publications/an-analysis-of-nices-optimised-decisions-from-2015-to-2024/

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Funding and Acknowledgements

This contract research report was commissioned and funded by The Association of the British Pharmaceutical Industry (ABPI).

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Executive Summary

The National Institute for Health and Care Excellence (NICE) is the body responsible for recommending medicines for use within the National Health Service (NHS) in England. One component of this is NICE's Technology Appraisal (TA) programme, wherein NICE assess the cost- and clinical-effectiveness of medical technologies and makes recommendations accordingly.

NICE states that 84% of its recommendations are positive; however, NICE categorises several decision outcomes as 'positive,' including recommended decisions, optimised decisions, and decisions allowing a medicine to be used in the Cancer Drug Fund (CDF). Further analysis of this statement reveals that 36% of NICE's positive decisions since 2000 have been optimised, excluding CDF decisions (NICE, 2025a).

Optimised decisions can have the effect of limiting patient access to medicines, as they often only recommend use of the medicine by a smaller population than for which the medicine is indicated in its marketing authorisation. However, the extent to which optimised decisions restrict patient access is unclear. Thus, the aim of this report is to better understand the impact of NICE's optimised decisions on patient access to medicines from January 2023 to December 2024.

We relied on O'Neill and Devlin's (2010) method for quantifying this impact, which involves calculating an M-score for each optimised decision:

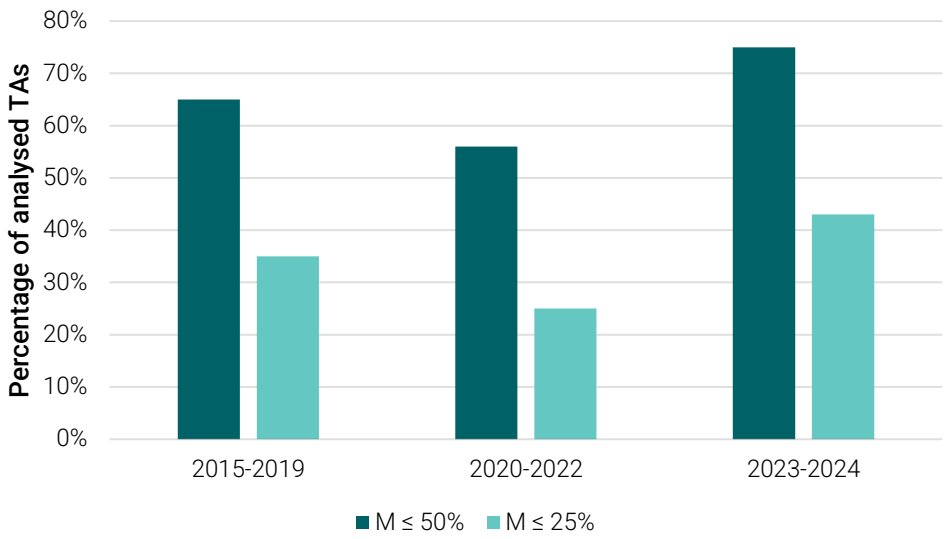
$$M = (p/P) * 100\%$$

where M is a measure of patient access, with 100% indicating full access and 0% indicating no access at all. P represents the population eligible for treatment as indicated in the medicine's marketing authorisation, and p represents the subset of this population for which NICE recommends treatment.

Between January 2023 and December 2024, NICE made 135 positive decisions, of which 64 (47%) were labelled as optimised, excluding CDF decisions. This result is consistent with the long-term trend of optimised decisions increasing as a proportion of positive decisions. Of the 64 optimised decisions made by NICE, 56 were carried forward for our analysis, and of those, 30 (47%) included sufficient information to allow for the estimation of M scores.

Among those 30 TAs, the mean M score was 31%, meaning that, on average, each optimised decision by NICE provides access to 31% of potential candidates for treatment, which compares to average M scores of 45% and 39% for the periods of 2020-2022 and 2015-2019, respectively. Moreover, we found that 77% of TAs recommended treatment for under half of the eligible patient population, with 43% having M scores below 25%. Between 2020 and 2022, these figures were 56% and 25%, and between 2015 and 2019, they were 65% and 35%. Thus, these results represent a decrease in patient access during the period of study. Figure 1 presents a visual representation of these changes.

FIGURE 1: M-SCORES BELOW 50% AND 25% FROM PREVIOUS OHE ANALYSES



The average level of patient access was particularly low for the following disease areas: infections (average M score 8%); neurological conditions (average M score of 15%); and diabetes and other endocrinal, nutritional and metabolic conditions (average M score of 17%). Medicines for digestive tract conditions, skin conditions, and eye conditions, in contrast, had average M scores over 50%.

Overall, these findings highlight the fact that optimised decisions are increasing in frequency and becoming more restrictive. A detailed examination of the drivers underlying this trend is beyond the scope of this analysis. An initial assessment of whether NICE report if optimisation is at the request of the company submitting evidence suggests that the factors underlying this trend are complex.

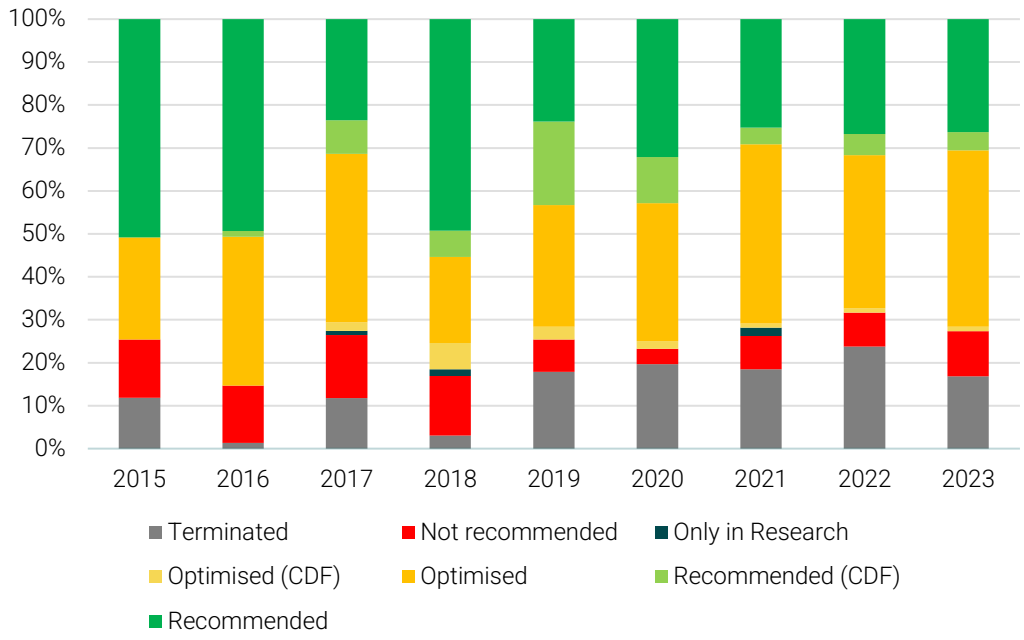
1 Introduction

The National Institute for Health and Care Excellence (NICE) plays a fundamental role in evaluating medicines for use in the National Health Service (NHS) in England. Among its most high-profile processes is the Technology Appraisal (TA) programme, wherein NICE considers the cost- and clinical-effectiveness of medicines and makes recommendations for their use, with the aim of ensuring that the NHS appropriately uses and allocates its limited resources.

For most of the TA programme's duration, NICE has issued five types of recommendations[1]:

- Recommended: The treatment is recommended for use by the NHS with no additional restrictions beyond those in its marketing authorisation.
- Recommended and optimised for use within the Cancer Drugs Fund (CDF): The treatment is available under conditional funding while more information is gathered on the medicine's effectiveness. This applies only to medicines for cancer.
- Optimised: The treatment is recommended for use by the NHS, but with additional restrictions compared to its full marketing authorisation.
- Recommended for use only in research: The treatment is recommended only for use in research.
- Not recommended: The treatment is not recommended for use by the NHS.

FIGURE 2: NICE-REPORTED DECISION OUTCOMES FOR TECHNOLOGY APPRAISALS AS A PROPORTION OF TOTAL DECISIONS FROM 2015 TO 2024



[1] *In 2024, NICE revised their recommendation structure to 4 "shorter and less complex" types to aid implementation. See the Discussion section for more details.*

NICE reports that 84% of its appraisal recommendations are positive (NICE, 2025a). However, a positive recommendation by NICE does not necessarily mean that all eligible patients, as defined in the medicine's marketing authorisation, will have access to the treatment. Indeed, NICE classifies three decision outcomes as "positive": recommended, recommended and optimised for use within the CDF, and optimised.

Since 2000, 36% of NICE's 'positive' decisions have been optimised, excluding CDF decisions (NICE, 2025a). Optimised decisions generally restrict one of three aspects of treatment: the population of patients eligible for treatment, the duration of treatment, or the care pathway (e.g., recommending a treatment only as an add-on). As such, optimised decisions can have the effect of limiting patient access to medicines, particularly when NICE's recommendation restricts the patient population eligible for treatment. The type of NICE decision outcome as a proportion of the total decisions made in each year since 2015 can be seen in Figure 2 above. From this, we observe that optimised decisions make up a large portion of each year's appraisals.

It should be noted that, while NICE ultimately determines the extent of use for a medicine, a decision to optimise may also be informed by the company's evidence submission. Most commonly, it is NICE that makes the decision to optimise a medicine with respect to its license—for example, where only a subgroup of patients meets the requirements for cost-effectiveness. However, company submissions to NICE sometimes include a population narrower than indicated in the marketing authorisation.

Previous research by OHE aimed to demonstrate how much optimised decisions limit patient access. Between 2015 and 2019, an average of 39% of the patient population potentially eligible for treatment were recommended for treatment in NICE's optimised decisions; this figure increased to 45% in the period between 2020 and 2022 (Henderson, 2023).

The aim of this report is to update this research with NICE's TAs from January 2023 through December 2024 in order to give an up-to-date view on how NICE's optimised decisions restrict patient access relative to marketing authorisations.

2 Methods

To determine the level of patient access associated with NICE's optimised decisions, we relied on a method developed and used by O'Neill and Devlin (2010). This measure of access is represented as an M-score, which is defined as:

M = (p/P) * 100%,

where M=100 represents full access, and M=0 represents no access at all. P is defined as the full set of patients indicated as potential candidates for treatment in the marketing authorisation for the medicine, while p represents the subset of patients within P who are deemed eligible for treatment in NICE's recommendation for the medicine.

To calculate M-scores, we used information presented in the guidance for each of NICE's optimised decisions. Under the "Tools and resources" tab of each TA, NICE often provides resource impact templates (RITs) for recommended and optimised medicines, with the purpose of these RITs being to aid NHS organisations in estimating the budget impact of these decisions and to help with local NHS resource planning. In most cases, these RITs provide sufficient information on patient populations to enable a comparison between the licensed indication under consideration and NICE's recommendation. In places where such information was not available (e.g., when NICE did not provide an RIT, or when the RIT did not include sufficient information for analysis), those TAs were excluded from our analysis.

NICE's website provides descriptions of the populations used for P and p. Indeed, for each TA, NICE describes the eligible population per its recommendation – i.e. the optimised population, or p — in the "Recommendation" section of its guidance; likewise, NICE describes the population indicated for treatment in the medicine's marketing authorisation (P) in the "Information about [medicine name]" tab of the guidance.

The values of P and p can be extracted from the medicine's RIT using the descriptions of the relevant populations. Each RIT provides an adaptable Excel model that can be used by local healthcare organisations to estimate the number of affected patients and the associated costs. Generally, these models include an estimate of the total population for the indication (i.e. the value of P), and, from there, a series of assumptions are applied to identify the 'recommended' patient population (i.e., the value of p).

An example of what is included in an RIT is provided in Table 1, which is from the RIT for TA999 'Vibegron for treating symptoms of overactive bladder syndrome' (NICE, 2024). This table demonstrates how percentage-based assumptions are used to refine the population at each stage. For instance, if 46,148,904 represents the adult population in England, 11.80% at level B indicates that 11.80% of the adult population has an overactive bladder, meaning a prevalence within this population of 5,445,571. In this case, the medicine is indicated for adults with overactive bladder syndrome, which is represented at level B and is used for the P value. The treatment is specifically recommended for adults with overactive bladder syndrome, only if antimuscarinic medicines are not suitable. The table represents this population using the proportion of people prescribed mirabegron annually, which is indeed prescribed to adults for whom antimuscarinic medicines are not suitable. Thus, level C represents the population eligible per NICE's recommendation, and it is used as the p value.

The calculation for Vibegron's M-score is (267,859/5,445,571) * (100%) = 4.92%. Rather than relying only on percentage reductions, we use absolute population figures for the M-score calculation, as this approach is useful for cases where more complex population estimations are required.

TABLE 1: EXAMPLE RESOURCE IMPACT TEMPLATE ASSUMPTIONS APPLIED TO ESTIMATE POPULATION FOR TA999

LEVEL	VARIABLES	NICE ASSUMPTION	ILLUSTRATIVE POPULATION	
A	Adult population		46,148,904	
B	Prevalence of overactive bladder	11.80%	5,445,571	Licensed population (P value)
C	Proportion of people prescribed mirabegron annually	4.92%	267,859	Optimised population (p value)

Source NICE 'Resource impact template: Vibegron for treating symptoms of overactive bladder syndrome (TA999)' (NICE, 2024)

For all optimised decisions where it was possible to calculate an M-score, an analyst indicated whether that calculation was straightforward or required some degree of subjectivity. For instance, some of the RITs do not include all the relevant assumptions needed to refine the overall population to match the exact descriptions of P and p from the marketing authorisation and NICE recommendation; in such instances, best estimates were used. For calculations that were not considered straightforward, a second analyst independently reviewed and validated the results. If any uncertainties remained, a third analyst conducted a final review, and any discrepancies were resolved through discussion.

This report focuses on TAs from January 2023 until December 2024. We identified the optimised decisions using NICE's published TA guidance from 01 January 2023 to 31 December 2024, wherein NICE indicates its decision for each TA. We verified that each decision labelled as 'Optimised' by NICE was indeed optimised through a comparison of the NICE recommendation to the medicine's marketing authorisation.

NICE had a total of 64 TAs with optimised decisions in this period, excluding optimised CDF TAs for comparability with previous OHE reports. However, during verification, we found that one of the TAs that was classified by NICE as an optimised decision was in fact a recommended decision, as its marketing authorisation aligned exactly with the NICE recommendation; thus, we excluded it as a recommended decision. As such, we considered NICE to have a total of 63 optimised decisions during this period.

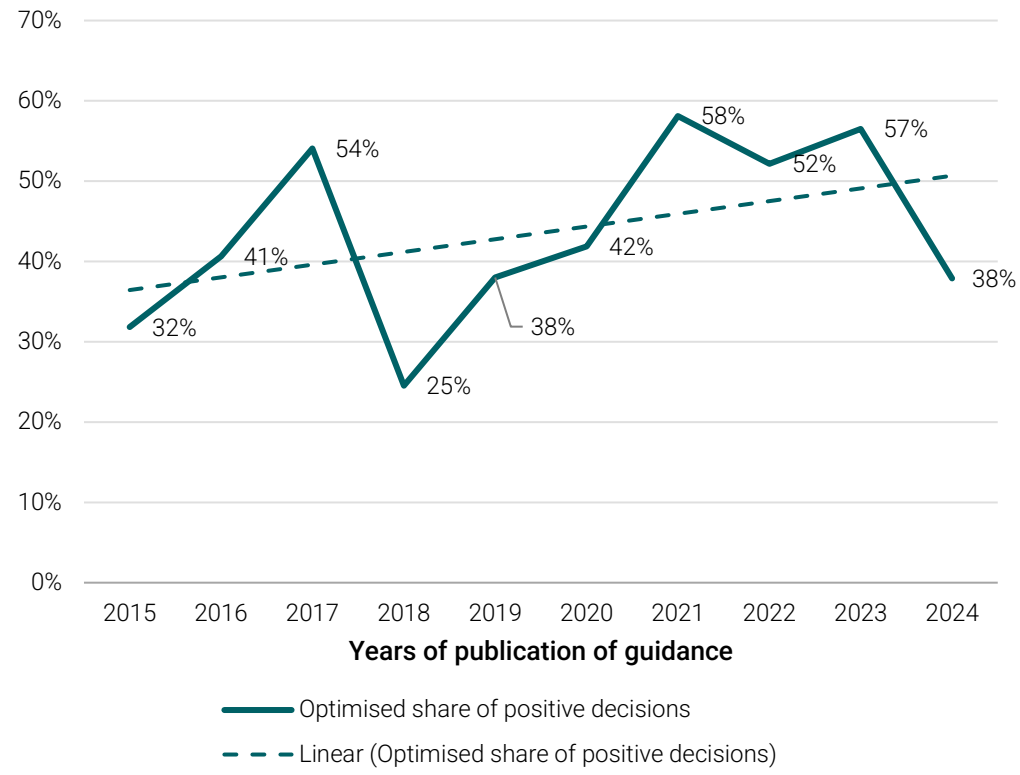
For this analysis, we excluded non-medicine technologies, of which there were three TAs. Additionally, we excluded four more optimised decisions that we found did not restrict patient populations. That is, in addition to restricting patient populations in its recommendations, NICE sometimes places limits on durations of use and care pathways (e.g., recommending a medicine only as an add-on treatment). While these recommendations do establish restrictions that are not included in the medicines' marketing authorisations, they do not restrict the patient population per se. Since this report focuses on how optimised decisions affect patient access by limiting the number of eligible patients, we excluded these cases from our analysis. This left us with 56 optimised decisions.

Of these, 30 TAs (54%) included sufficient information (i.e. included a resource impact template and sufficient information within that RIT) to calculate an M-score and were taken forward for further analysis.

3 Results

In the period of study – 01 January 2023 to 31 December 2024 – NICE made a total of 135 positive decisions, of which 64 (47%) were classified by NICE as optimised, excluding CDF optimisations. Figure 3 below uses NICE's own reported decisions to compare shares for the past 10 years. The linear trend, plotted with a dashed line, illustrates an increasing long-term trend in the share of optimised decisions as a share of positive decisions. Figure 2 also evidences the fact that the most recent four years have seen the highest proportion of optimised decisions.

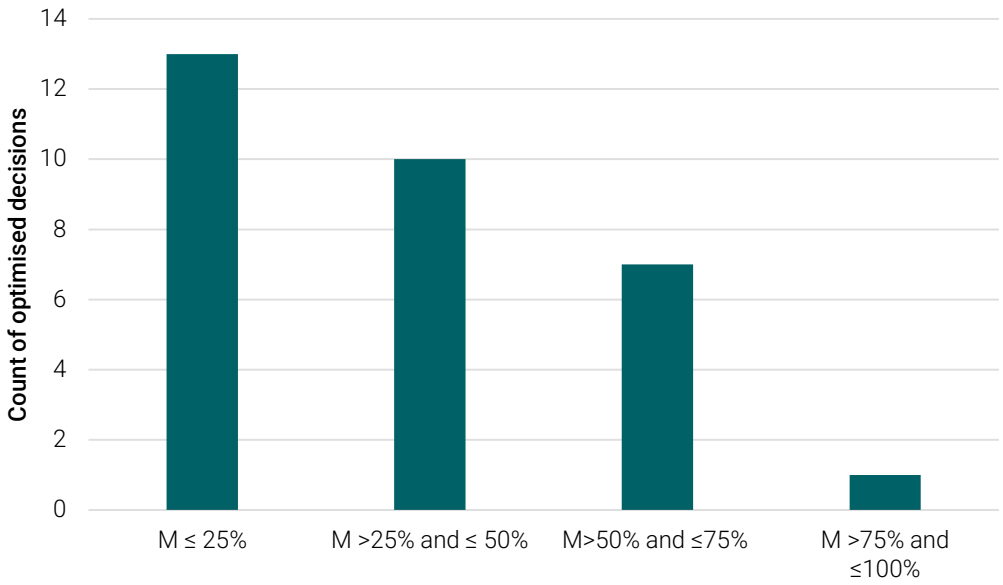
FIGURE 3: OPTIMISED DECISIONS AS A SHARE OF POSITIVE DECISIONS (NICE REPORTED)



As previously mentioned, of these 64 optimised decisions, we carried forward 30 for further analysis. Among these, the mean M-score was 31%, meaning that, on average, each optimised decision by NICE provides access to 31% of the total population for which the medicine is indicated in its marketing authorisation. This figure compares to 45% between 2020-22 and 39% between 2015-19, indicating an overall decrease in access during this time period. The median M-score from 2023-24 was 27%.

Figure 4 provides the distribution of M scores across the 30 optimised decisions that were analysed. We found that 77% of NICE's optimised decisions recommended treatment for half of the eligible patient population. Specifically, 43% had M scores below 25%, and 33% had M scores between 25% and 50%. Of those affording access to more than half the eligible patient populations, 20% had M scores between 50% and 75%, and 3% (i.e. one decision) had an M score between 75% and 100%.

FIGURE 4: DISTRIBUTION OF THE PRODUCT-SPECIFIC M SCORES FOR NICE OPTIMISED DECISIONS, 2023-24



Observing M scores across disease areas (Figure 5) can provide further context for trends in optimised decisions. There is likely to be commonalities in the drivers of optimisation for medicines with comparable indications and therefore they are likely to have similar M scores. For example, optimised decisions may be driven by what other treatments are available and how inferior (if at all) they are to the medicine that's the subject of the optimisation. In disease areas where a relatively large array of products is available, a new medicine may have limited added value except for specific patient subgroups.

Recommendations for infections (average M score of 8%); neurological conditions (average M score of 15%); and diabetes and other endocrinal, nutritional and metabolic conditions (average M score of 17%) appear to be especially restrictive relative to license. In contrast, three disease areas – digestive tract conditions, skin conditions, and eye conditions – had average M scores over 50%, indicating that, on average, optimised recommendations in these areas provided access to more than half of the eligible patient population. However, as some M score estimates are based on a limited number of decisions, these findings should be interpreted with caution.

FIGURE 5: ESTIMATED AVERAGE M SCORE BY DISEASE AREA, 2023-24

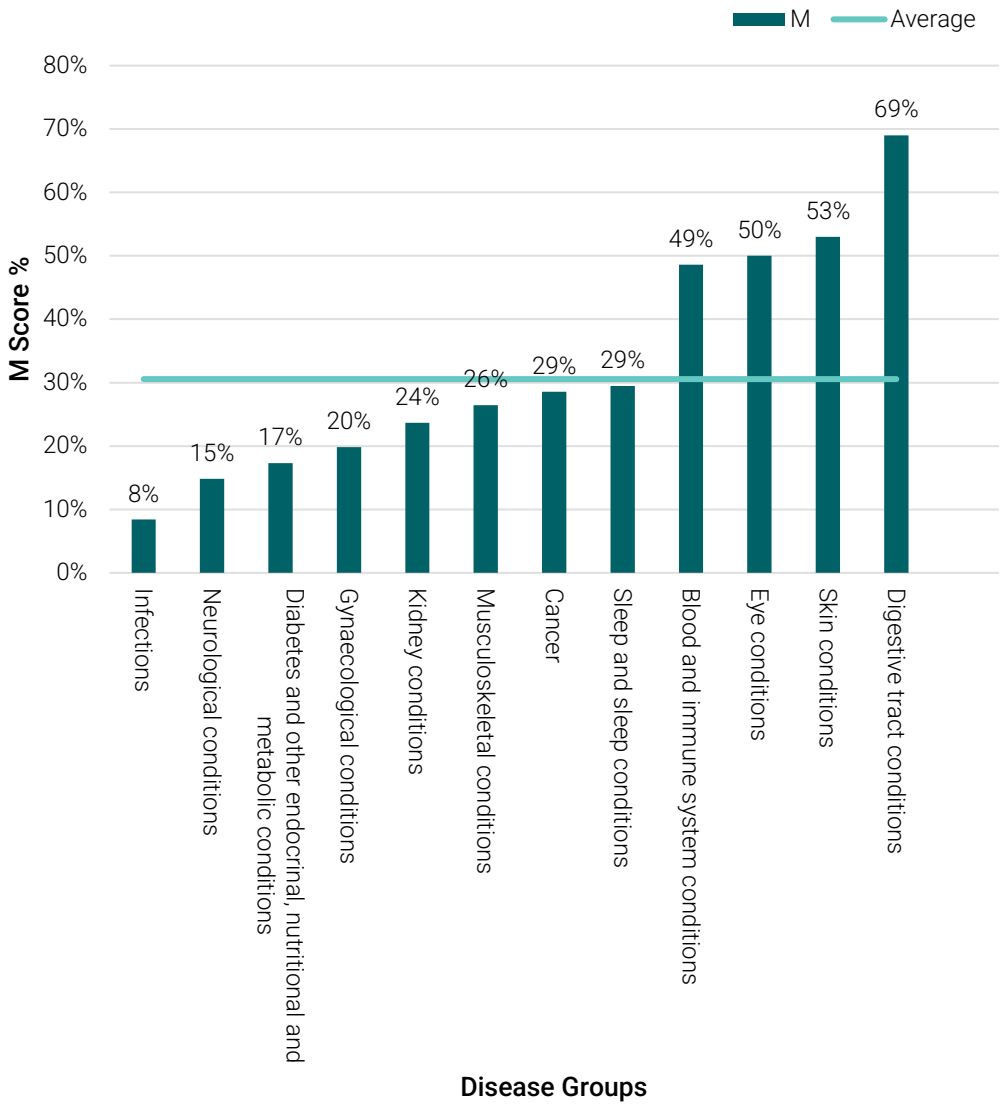


Figure 6 below presents the yearly average M scores from 2015 to 2024. The graph shows roughly an upward trend in M scores between 2015 and 2022. However, the years included in this analysis mark a return to roughly 2015-2016 levels, indicating that, more recently, optimised decisions have become increasingly restrictive in limiting potential candidates' access to medicines.

FIGURE 6 ESTIMATED AVERAGE M SCORE BY YEAR, 2015-2024

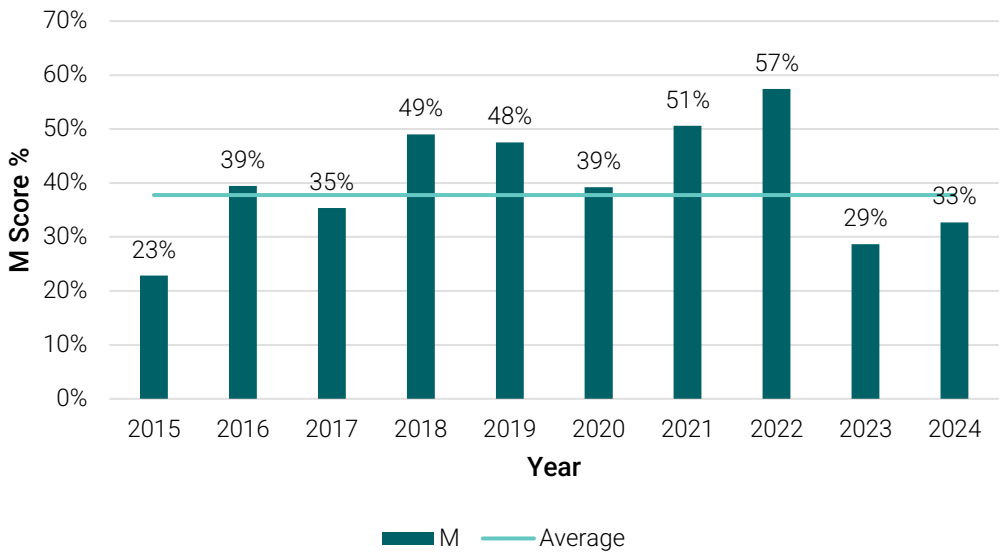
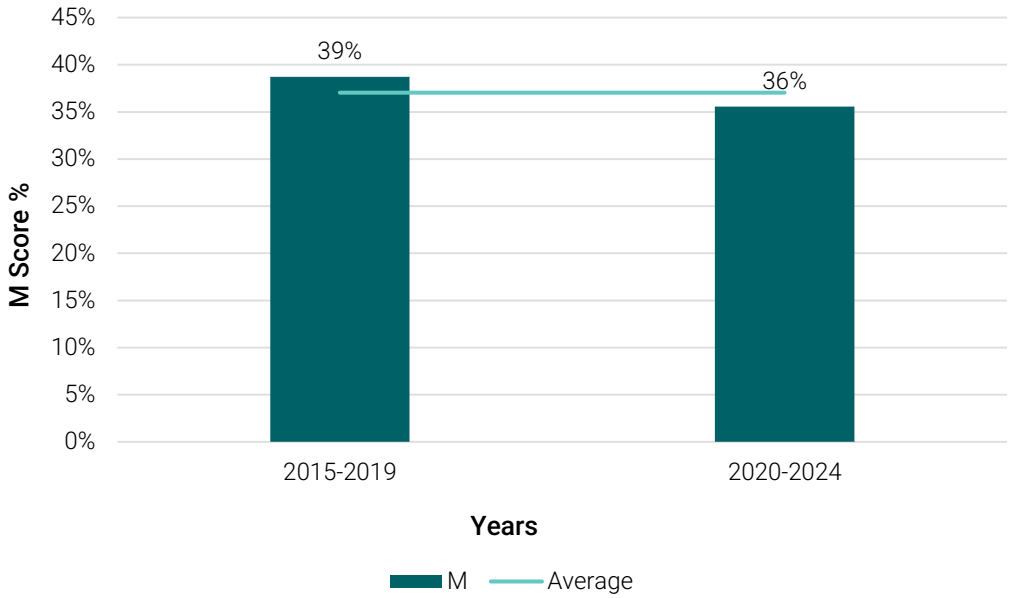


Figure 7 illustrates that, while average M scores in 2023 and 2024 are almost half that of 2022, the most recent five-year averages are roughly the same, with only a slight decrease between 2020-24 compared to 2015-19.

FIGURE 7 ESTIMATED AVERAGE M SCORE BY FIVE-YEAR INCREMENTS, 2015-2024



4 Discussion

Overall, our results suggest that within the past two years, NICE's optimised decisions have become increasingly restrictive, with 2023 and 2024 having the lowest average M scores since 2015. This ultimately suggests that, on average, each optimised decision has rendered fewer potential patients eligible for treatment. Notably, this result is a divergence from the trend between 2015 and 2022, wherein the average M score each year followed a general upward trend. This could be indicative of some type of shift in NICE's decision-making or in the overall pharmaceutical landscape over the past two years.

Moreover, we also found that almost half (47%) of NICE's 'positive' decisions during this period were optimised. Indeed, NICE made more optimised decisions than recommended ones. This result is part of an increasing trend by NICE in issuing optimised decisions, as Figure 2 highlighted that the most recent four years have seen the largest percentage of optimised decisions as a proportion of positive decisions. This result is also over 10 percentage points higher than NICE's long-term average, as 36% of all positive decisions over the past 25 years have been optimised. This, too, represents a decrease in patient access, as more decisions are excluding potentially eligible patients from treatment. Combined with the above result, this indicates that NICE is making more optimised decisions that are, on average, excluding more patients.

Table 2 illustrates this point through a breakdown of the M scores from previous OHE analyses on optimised decisions. As evidenced by the table, in addition to having the lowest mean M score, the period currently under study also saw the highest proportion of M scores under 25% and 50%.

TABLE 2: COMPARISON SUMMARY OF M SCORES WITH EARLIER ANALYSES

	2023-24 (Current Analysis)	2020-22 (Henderson, 2023)	2015-2020 (Bulut, O'Neill and Cole, 2020)
M>75 and ≤100	1 (3%)	4 (25%)	4 (10%)
M>50 and ≤75	6 (20%)	3 (19%)	10 (25%)
M>25 and ≤50	10 (33%)	5 (31%)	12 (30%)
M≤25%	13 (43%)	4 (25%)	14 (35%)
Total analysed	30	16	40
M≤50%	77%	56%	65%
Mean M Score	31%	45%	39%

The scope of this report is limited to understanding how much optimised decisions limit access, rather than explaining reasons for optimisation. Indeed, NICE makes optimised decisions for several reasons. NICE commonly issues optimised decisions when its committee has decided that the medicine is only cost-effective when used for subpopulations who cannot tolerate or are resistant to other drugs, or when the committee has similarly decided that a medicine is only cost-effective when use is restricted to subpopulation with certain characteristics. Additionally, some optimised decisions are made in instances where sufficient evidence has only been provided for NICE to recommend use in a certain subgroup. Without a comprehensive review of the reasons for optimisation, it is difficult to explain the shifts in these results.

This paper aims to estimate the level of access associated with optimised decisions. However, these estimates should be interpreted with a degree of caution, given limited information availability. As previously mentioned, only 56% of TAs had sufficient information for inclusion in this analysis. This compares to 21% in our 2020-22 analysis and 36% in our 2015-19 report (Henderson, 2023; Bulut, O'Neill and Cole, 2020). Though this is an improvement in information availability, several TAs have still been excluded from this analysis, and there is no way of knowing if those that have been excluded have systematically higher or lower M scores than those included in this report.

Additionally, we based our M score calculations solely on NICE's RITs, which represent NICE's own assessment of patient eligibility as outlined in its guidance. We assumed that the data and underlying assumptions in these templates were generally reliable.

However, because these templates are designed for estimating financial impact rather than explicitly defining patient populations, we faced some challenges in directly aligning the populations used in the RITs with the populations described as p and P in the NICE recommendation and marketing authorisation, respectively. In these instances, we had up to three analysts independently review the RITs to inform best estimates. To further minimise the impact of this limitation, we excluded TAs where we felt a best estimate could not conservatively be made.

It should also be noted for future analyses that, during 2024, NICE revised its decision categories. Specifically, the distinction between a medicine receiving an optimised or recommended use decision was combined into the category "can be used" (NICE, 2025b). The four revised categories of decisions to be applied across all types of guidance are:

- Can be used.
- Can be used during either:
  - a managed access period (for technology appraisals and highly specialised technologies), or
  - evidence generation period (for medical technologies, diagnostics, early value assessments and interventional procedures).
- More research is needed.
- Should not be used.

For this analysis, all TAs were classified using the previous decision categories, but, in the future, it will be important that decisions that restrict use are still reported as optimised so as to ensure full transparency. Using the methodology of comparing licenses with the scope of recommendation, it will still be possible to identify instances of medicines receiving "can be used" decisions that are in fact optimised.

The trend for more, and increasingly restrictive, optimised decisions raise questions about the drivers determining HTA decisions. The causes underlying this current trend may highlight issues for NICE HTA methods and processes that need to be addressed. There may be space for increased stakeholder engagement by NICE to ensure that optimised decisions do not unduly restrict access to effective treatments.

5 Conclusions

Our analysis indicates that NICE's optimised decisions have become increasingly restrictive in recent years, with 2023-24 showing the lowest average level of access since 2015. Ultimately, this suggests that a growing proportion of patients who would otherwise be eligible for treatment under a medicine's marketing authorisation are excluded under NICE's recommendation. Additionally, nearly half (47%) of NICE's 'positive' decisions during this period were optimised, which is consistent with NICE's longer-term shift towards making more optimised decisions. Together, these findings highlight a trend toward more restrictive access to medicines. While the reasons behind these shifts remain unclear, future research could explore the motivating factors.

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