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NICE ‘Optimised’ Decisions: What is the Recommended Level of Patient Access?

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Executive Summary

The National Institute for Health and Care Excellence (NICE) makes recommendations for use of medicines and treatments in the National Health Service (NHS) in England based on their clinical and cost-effectiveness, through their Technology Appraisal (TA) programme. NICE state that 82% of TA recommendations are positive (i.e. some level of patient access is recommended, either in line with licence or with some modifications). This does not include terminated appraisals (of which there have been 52); if included, the proportion of 'positive' recommendations among all appraisals initiated reduces to 77%. In the 20 years between 2000 and 2019, 932 recommendations were made through 616 appraisals. Excluding terminated appraisals:

- 54% were 'recommended' (n=475)
- 24% were '**optimised**' (n=213)
- 4% were recommended (or optimised) within the Cancer Drugs Fund (CDF) (n=34)
- 3% were recommended for use only in research (n=28)
- 15% were not recommended (n=130)

Excluding CDF drugs, 'optimised' decisions represent 31% of all positive recommendations made by NICE between 2010 and 2019; in the last five years, this has risen to 43%. The 'optimisation' of a recommendation involves a narrowing of the eligible patient population. This can be for various reasons, for example where the drug is found only to be cost-effective in a sub-group of patients; sometimes these conditions are specified by the manufacturer in their submission. The purpose of this research is to quantify the restriction to patient access (relative to licence) associated with NICE optimised decisions, and in doing so to update previous research in this area which examined NICE optimised decisions between 2006 and 2009 (O'Neill and Devlin, 2010).

To quantify the recommended level of patient access relative to licence, we calculated the 'M-score' as defined by O'Neill and Devlin (2010) for optimised recommendations between 2010 and 2019:

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

where M is a measure of patient access level (0=no access, 100=full access), P is the set of patients considered in the guidance as potential candidates for treatment (given the licensed use and the scope of NICE's appraisal), and p is the patient subset for whom NICE did recommend treatment.

Given limitations in data availability between 2012 and 2014 (over which time the information required to calculate M was not available), we restricted our sample to the five-years between 2015 and 2019. Of the 112 treatments that received an optimised recommendation over that period, 40 (36%) included sufficient information that allowed the estimation of M.

Of those 40 decisions 65% had an M score of ≤ 50 , 35% had an M score of ≤ 25 and 12.5% had an M score of ≤ 10 . The average (mean) M score across the whole sample was estimated to be 39. In other words, on average only 39% of the patient population that was potentially eligible for the treatment under review were recommended treatment in NICE's final 'optimised' recommendation. In about two-thirds (65%) of optimised recommendations for which information was available, NICE recommended use for less than half of patients for whom the medicine is licensed. The recommended level of patient access was particularly low for medicines treating autoimmune

disorders (average M: 10), cardiovascular conditions (average M: 18), and infectious diseases (average M: 24), and relatively higher for neurology (average M: 59) and cancer medicines (average M: 51). Compared with a similar analysis conducted ten years ago (O'Neill and Devlin, 2010), M scores appear to be slightly higher (in the current analysis 65% of optimised decisions recommend use in less than half the eligible patient population, versus 71% in the 2010 research).

The categorisation by NICE of recommendations as 'optimised' appears to be increasing. Whilst this may be well justified on cost-effectiveness grounds, this analysis has demonstrated that patient access associated with these decisions can be low, and this may warrant the publication of further detail in the communication of NICE's decisions.

1 Background

Over the past twenty years, the National Institute of Health and Care Excellence (NICE) has established itself as a global leader in health technology assessment (HTA), with a high volume of outputs across its HTA programmes. Among its most high profile is NICE's Technology Appraisal (TA) programme, through which NICE makes recommendations on the clinical and cost-effectiveness of medicines and treatments, with the aim of making sure that the National Health Service (NHS) uses its resources fairly and effectively (NICE, 2020a). In summarising their TA recommendations, NICE states "We approve the majority of medicines and treatments: 82% of our appraisal recommendations are positive". However, these include several types of positive recommendation: 'recommended', 'recommended for use in the CDF' and 'optimised' (NICE, 2020a).

Between 2000 and 2019, NICE reviewed 616 technical appraisals and made 932 individual appraisal decisions (Figure 1)¹. Excluding the 52 that were terminated, 475 (54%) decisions were 'recommended', 213 (24%) decisions were 'optimised', 34 (4%) were recommended (or optimised) for inclusion in the Cancer Drugs Fund (CDF), 28 (3%) were recommended for use only in research, and the remaining 130 (15%) were not recommended (See Appendix for full details). Although terminated appraisals do not represent a decision outcome (and the reasons for non-submission are not clear), if those 52 terminated appraisals are included, the overall proportion of 'positive' decision outcomes from all appraisals that are started is reduced from 82% to 77%. In the below timeline we also indicate key changes to the technology appraisal process, which could plausibly impact the number or type of recommendations made by NICE.

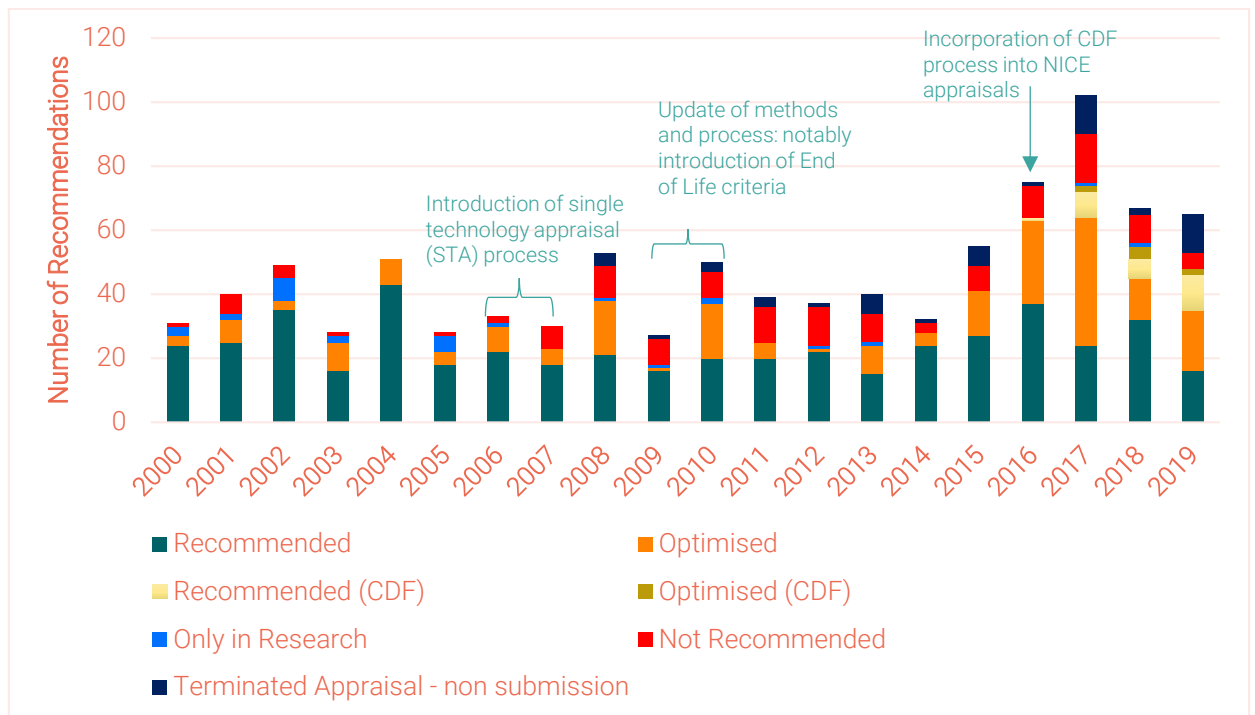


FIGURE 1 NICE TA RECOMMENDATIONS, 2000-2019

¹ Data obtained from information publicly released by NICE summarising all recommendations (NICE, 2020). Data have been re-calibrated to calendar years.

1.1 NICE ‘optimised’ recommendations

Recommendations that are described by NICE to be *positive* include those decisions that were:

- Recommended,
- Recommended or optimised for use within the CDF, and
- Optimised

In contrast to NICE ‘recommended’ decisions for which the recommendation is either in line with the marketing authorisation or ‘in line with how it is used in clinical practice’, an *optimised* recommendation is described as:

“The technology is recommended for a smaller group of patients than originally stated by the marketing authorisation. Sometimes the committee decides that a drug is only cost-effective as a treatment option for a specific group of people, for example, those who are resistant to or can’t tolerate other drugs.” (NICE, 2020b)

NICE positively recommended 722 of the technologies that were appraised between 2000 and 2019. A closer examination of these decisions shows that 31% of positive recommendations were optimised (either within the mainstream optimisation recommendation (213) or within the CDF (8)). From Figure 2 it is evident that the proportion of positive recommendations by NICE that have been ‘optimised’ has varied year-on-year, but there has been a general trend upward – as observed by the three-year moving average curve – particularly over the last five years where 43% of positive recommendations have been ‘optimised’.

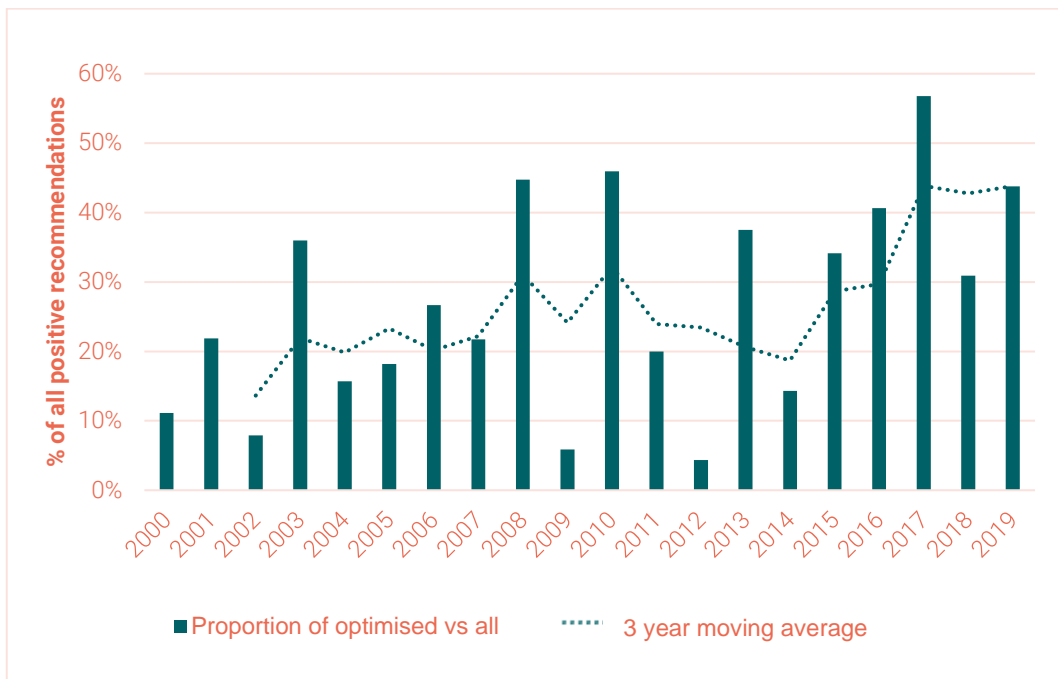


FIGURE 2 ‘OPTIMISED’ DECISIONS AS A PROPORTION (%) OF ALL POSITIVE RECOMMENDATIONS, 2000-2019

For our analysis of patient access, we concentrated on NICE decisions that have been published in the last ten years (2010 to 2019). Over that time there were a total of 148 optimised decisions², the majority of which were for technologies relating to autoimmune disorders (35%; n=52) and cancer (26%, n=39). If we compare this with the proportional representation of those diseases among *all* TAs within the same timeframe, important differences can be observed. For example, over a third of all optimised decisions related to treatments for autoimmune disorders, whereas only 17% of all TA decisions related to this disease category. The opposite relationship is observed for cancer-related TA decisions, which represent just over a quarter of optimised decisions compared with are nearly half of all TA decisions. These differences are demonstrated in Figure 3 and Figure 4, below.

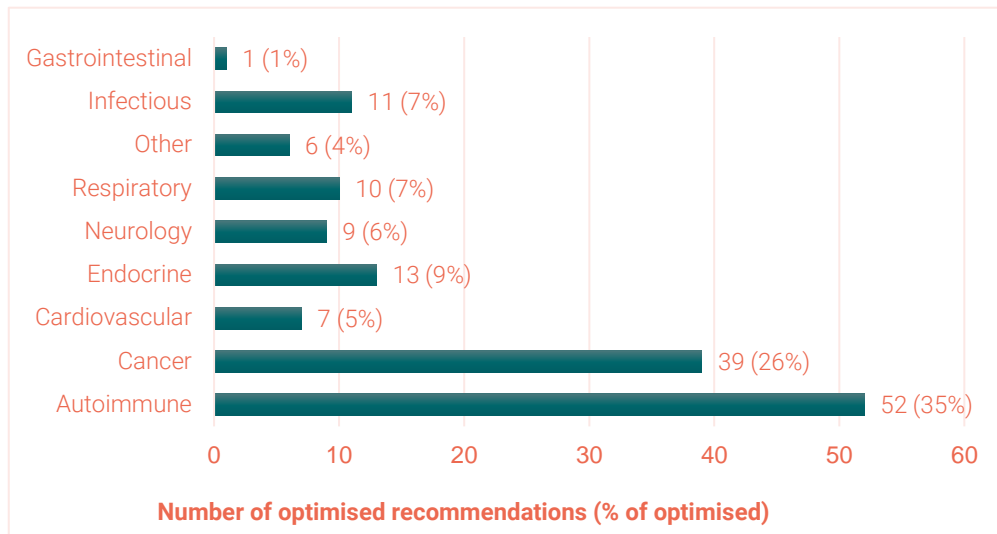


FIGURE 3 OPTIMISED DECISIONS BY DISEASE, 2010-2019

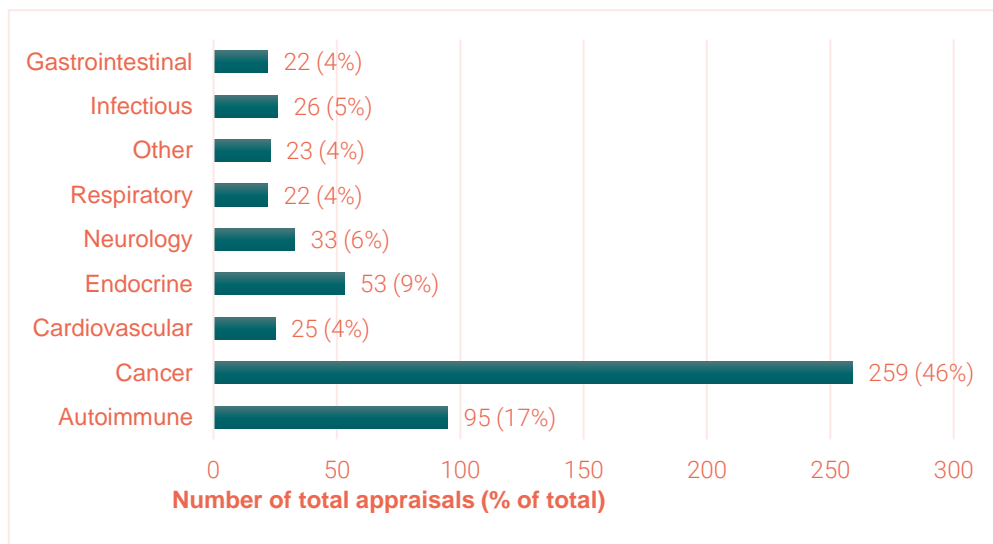


FIGURE 4 ALL APPRAISALS CATEGORISED BY DISEASE, 2010-2019

² This excludes the 8 optimised recommendations within the CDF; this is because for CDF drugs we could not capture the information required for the calculation of the M score.

The differences in the proportional representation of disease areas among optimised decisions compared with other types of NICE TA outcome is notable, and could be explained by restrictions specified by NICE through optimised decisions in relation to the sequencing of medications (line of therapy) which is more/less relevant in some disease areas compared with others, or the breadth/narrowness of the scope of NICE appraisals in different disease areas. In Figure 5 we outline decision outcomes for each disease area³, which shows that there is a high proportion of optimised recommendations for autoimmune, infectious diseases and respiratory conditions.

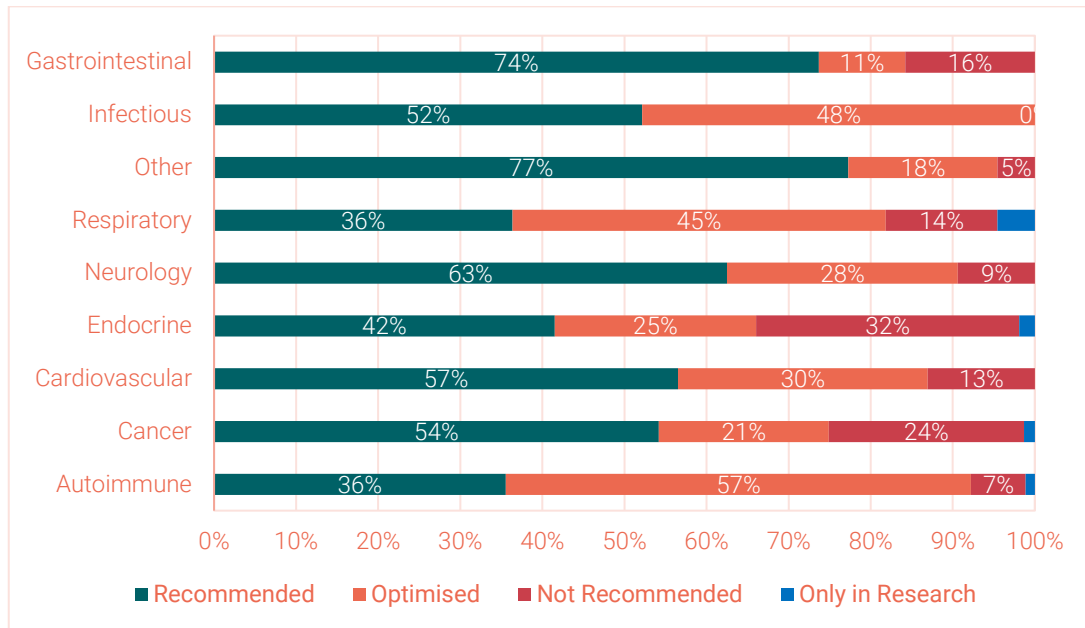


FIGURE 5 TA DECISION OUTCOME BY DISEASE, 2010-2019

The main focus of our analysis is to elucidate the meaning of an ‘optimised’ recommendation in terms of the restriction to patient access (relative to marketing authorisation) that optimised recommendations entail, which is currently not well understood.

³ Note that Figure 5 excludes terminated appraisals (whereas Figure 4 includes terminated appraisals). For cancer: CDF recommended and CDF optimised decisions are captured within the broad ‘recommended’ and ‘optimised’ categories.

2 Methods

In an article published by O'Neill and Devlin (2010), the authors describe a method to measure the degree of patient access associated with NICE optimised decisions between 2006 and the end of 2009. The measure is labelled the 'M' score, and is defined as:

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

where M is a measure of the level of patient access (0 = no access, 100 = full access), P is the set of patients considered in the guidance as potential candidates for treatment (given the EMA licensed use and the scope of NICE's appraisal), and p is a subset of those patients, for whom NICE did recommend treatment.

The sources of information used to estimate P and p are NICE's resource impact templates (which are often included in the materials produced by NICE to support each TA). The purpose of these resource impact templates is to assist NHS organisations (e.g. Clinical Commissioning Groups) to anticipate the budgetary impact of NICE's recommendations, and to assist with local NHS resource allocation and planning. In many (but not all) instances, the information provided to support these cost estimates enables a comparison to be made between the licensed indication under consideration and the actual recommendation made by NICE.

The initial step was to capture all NICE decisions for the period of study (2010 to 2019) using NICE's taxonomy of decision outcomes (NICE, 2020a). For some appraisals, where more than one medicine has been assessed, multiple decision outcomes may be reached for each TA. For example, in TA217 'Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease', NICE report that only memantine received an optimised decision. Therefore, we calculate the M score for each individual optimised decision (rather than assessing the appraisal as a whole).

All data relevant to the calculation of 'M' was obtained from the NICE website. From the TA documentation we captured the scope of NICE's appraisal from the 'Guidance' section, and the licensed indication from the section 'The technology(ies)'. In addition, resource impact templates (where available) were accessed, but these were not available for all optimised decisions. In many instances this is because the anticipated resource impact is not sufficiently significant to require planning, and therefore NICE does not provide this resource. It was also the case that for all appraisals prior to 2015, resource impact templates were not available from the NICE website at the time of analysis.

Resource impact templates tend to adopt a consistent methodology. Their aim is to help support specific local health organisation areas to estimate the costs associated with the implementation of NICE guidance. To this end, they supply an excel model that can be adapted to enable each local area to estimate the number of patients and costs associated with the guidance. Our starting point was the estimate of the total population for the indication, which is provided by NICE. Assumptions are then applied to capture the 'recommended' population. Table 1 below is taken from the resource impact template for TA479 'Reslizumab for treating severe eosinophilic asthma'. In the table the percentages in the column 'NICE assumption' reduce the population figure in the previous level by the fraction specified. For example, if the population is 100,000, then the next level 'prevalence of asthma' reduces this population to 7,960 to reflect the assumption that 7.96% of the population has asthma. In this case the licence (and scope of the appraisal) for the medicine is for patients with severe uncontrolled asthma, represented at level E in the table, and which we use for the P value. The specific restriction of recommended use associated with this medicine is for patients experiencing three or more exacerbations in the last 12 months, level F in the table. The M score in this instance

will be $((51/202)*100) = 25\%$. We use population numbers rather than the percentages associated with the assumptions to calculate the M score as many cases have more complex models for estimating the population, for example combining incidence and prevalence figures.

TABLE 1 EXAMPLE: RESOURCE IMPACT TEMPLATE ASSUMPTIONS APPLIED TO ESTIMATE POPULATION FOR TA479

Level	Variables	NICE assumption	Illustrative population	
A	Adult population		100,000	
B	Prevalence of asthma	7.96%	7,960	
C	People with severe asthma	7.50%	597	
D	People with blood eosinophils 400 cells per microlitre or more	53.40%	319	
E	People with uncontrolled asthma	63.50%	202	licensed population (P value)
F	People experiencing 3 or more exacerbations in the last 12 months	25.00%	51	optimised population (p value)

Source NICE 'Resource impact template: Reslizumab for treating severe eosinophilic asthma (TA479)' (NICE, 2017)

For all cases where an M score was obtained, calculations were made by one analyst and validated by a second analyst. Differences in results were resolved through discussion.

To maintain comparability with the previous analysis (O'Neill and Devlin, 2010) we have not included decisions reported as 'Cancer Drugs Fund Optimised', which have different characteristics to other 'Optimised' decisions; specifically, they optimise use of the medicine to match an agreed plan for evidence gathering for a subsequent review.

The intention of this report is to quantitatively summarise the degree of restriction, relative to licence, for medicines receiving an optimised use recommendation by NICE. This analysis does not address, nor systematically analyse, underlying explanations for the restriction. In their description of optimised decisions NICE note "(s)ometimes the committee decides that a drug is only cost-effective as a treatment option for a specific group of people, for example, those who are resistant to or can't tolerate other drugs". This type of optimisation can be seen in technology appraisal TA390, where NICE consider the use of SGLT2 inhibitors. These were a new class of diabetes medicines in a therapy area with a number of established medicines. These medicines have a licence for use in diabetes if metformin is contraindicated. In their consideration of the evidence NICE note that the incremental cost effectiveness ratios (ICER) of these medicines relative to two other classes of medicines, pioglitazone and sulfonylureas, were above their threshold of £30,000. Therefore, they recommend use of SGLT2's only if patients find that use of pioglitazone or sulfonylureas is not appropriate: a smaller group of patients than the licensed indication.

A related type of optimisation decision is where use is restricted to a subgroup of patients with specific characteristics for whom use is considered to be cost effective. For example in TA346, Aflibercept for treating diabetic macular oedema, a distinction is made between patients with central retinal thickness (CRT) of greater than 400 micrometres, and those where the thickness is below this level. In the former group the intervention is cost effective, with a calculated ICER of £22,000, whilst for the latter it is £48,300. Hence use was optimised to the greater than 400 micrometres group.



These are the most common types of optimised decision recommendation, but other cases include where the clinical evidence is not available for the whole scope of the licence, or where the manufacturer submits evidence for a subgroup of patients. For example TA474, Sorafenib for treating advanced hepatocellular carcinoma. The committee noted that the clinical evidence was from a trial where patients were predominately stage C disease and with good liver function, and therefore refined ('optimised') their recommendation to specify patients with these characteristics.

3 Results

Our initial sample of optimised decision data was from January 2010 to December 2019, over which period 148 optimised recommendations were made; data availability was such that we were able to calculate M for 57 of those decisions (39%). A variation in data quality was observed between 2010-2014, particularly between 2012-2014 where all optimised decisions reviewed had missing values for either P and/or p. Therefore, for data continuity and quality, we included the 112 optimised recommendations that were made over the five-year time period between January 2015 and December 2019.

Of the 112 optimised recommendations that were made between 2015 and 2019, 40 (36%) had sufficient information to estimate the M score. Of the 40 decisions analysed, the average (mean) M score across the whole sample was estimated to be 39. That is, on average only 39% of the patient population that was potentially eligible for the treatment under review were actually recommended treatment in NICE's final 'optimised' recommendation. The median M score was 36.

In Figure 6 below we provide the distribution of M scores across the 40 decisions that were analysed.

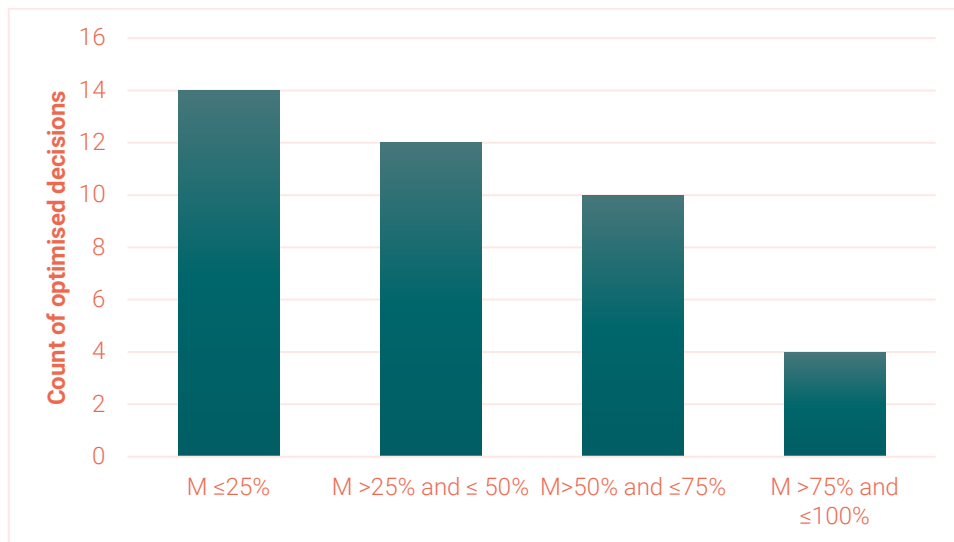


FIGURE 6 DISTRIBUTION OF THE PRODUCT-SPECIFIC M SCORES FOR NICE OPTIMISED RECOMMENDATIONS, 2015 - 2019

Of the 40 optimised decisions analysed, 14 (35%) had an M-score of less than 25, 12 (30%) had an M-score between 25 and 50, 10 (25%) had an M-score of between 50 and 75 and 4 (10%) had an M-score of between 75 and 100. In other terms, for 65% of the optimised decisions analysed (n=26), NICE recommended that the treatment under appraisal should be available to less than half of eligible patients.

Figure 7 below shows the yearly average (mean) estimated M scores between 2015 and 2019, and demonstrates an upward trend in M scores over that time period.

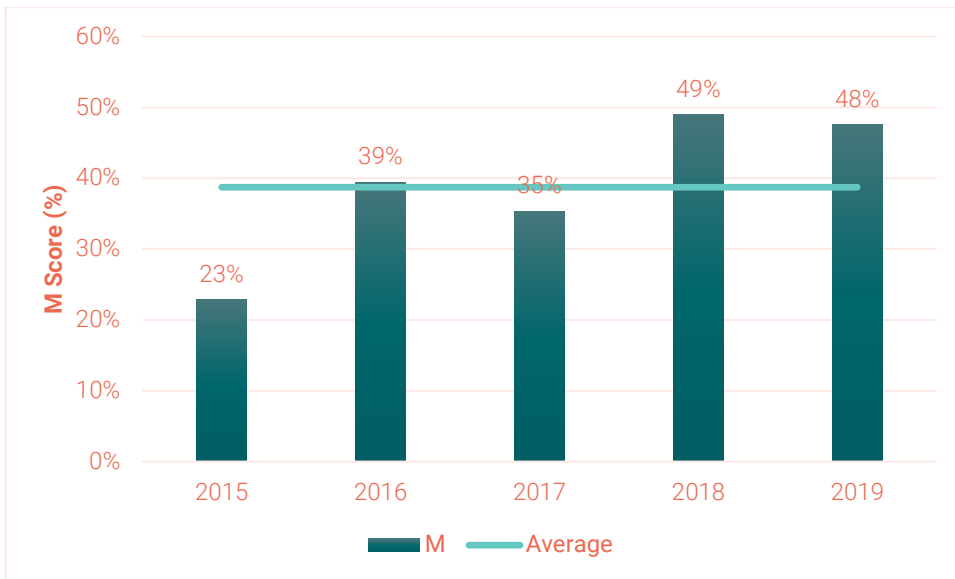


FIGURE 7 ESTIMATED AVERAGE M SCORE BY YEAR, 2015 – 2019

By observing the mean M-scores across disease areas (Figure 8), we can see that optimised recommendations for autoimmune (average M=10) and cardiovascular (average M=18) diseases appear to be particularly restrictive relative to license. Average M scores for Neurology- and Cancer-related optimised decisions were 59 and 51, respectively. That is, neurology and cancer were the only diseases for which on average over half of potential candidates for treatment were recommended access as part of the optimised decisions. However, it should be noted that some of these estimates are on the basis of a small number of optimised decisions (see Figure 3) and therefore differences should be interpreted with caution.

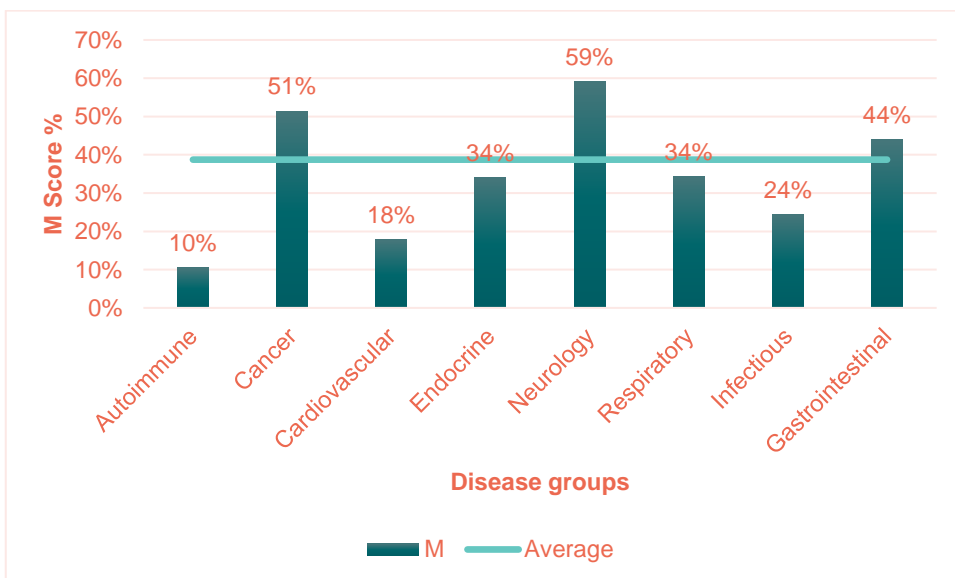


FIGURE 8 ESTIMATED AVERAGE M SCORE BY DISEASE AREA, 2015 - 2019

Another way to summarise the overall level of patient access associated NICE optimised decisions is to consider the overall P (all of the patient population considered in scope for all of 40 included optimised decisions over the last 5 years) and overall p (all patients actually recommended treatment within those decisions). This yields an overall M score of 18%, which means that across all of the optimised recommendations considered, NICE recommended that treatments be used for 18% of the total patient population under consideration. The reason for the difference between this and the 'average M' of 39% must be due to treatments with particularly low measures of M having relatively large potential patient populations, thus proportionally having a bigger impact on the M score and bringing it down.

4 Discussion

Over the coming year, NICE is consulting on and updating its methods, which have not been updated since 2013. One metric to inform discussions around these methods should be an accurate picture of the patient access that is supported by NICE’s recommendations.

Optimised recommendations are made for a number of reasons, including to limit the use of a treatment to a subset of patients for whom it is considered to be cost-effective, or to reflect the availability of clinical evidence. The stratification of the potential population, for example according to line of therapy, is more common in some disease areas than others. This is the case for diseases that are either progressive in, or have a spectrum of, severity and where choice of treatment options provide a range of trade-offs between benefits and risks, and can reflect standard of care. This can be illustrated using the example of the various appraisals undertaken to assess the use of biologic treatments for rheumatoid arthritis (RA). This is a progressive disease the symptoms of which have an increasingly life limiting effect. Many patients initially presenting with symptoms are effectively managed on older, generically available, medicines known as disease modifying anti-rheumatic drugs (DMARDs). But a proportion of patients will find these medicines inadequate and experience worsening of symptoms. For these patients, a family of biologic treatment alternatives became available and were assessed by NICE. Compared with the DMARDs these medicines were more effective in addressing the underlying causes of arthritis but had a higher cost and were associated with more side effects. The licence for many of these new medicines was for patients with moderate to severe disease. NICE used a clinical test, the Disease Activity Score (DAS28), to stratify patients effectively placing use of these medicines in the pathway for severe patients only. This restriction, relative to licence, meant that the M scores for these medicines was low. These medicines received licences for a variety of diseases, attracted a number of appraisals from NICE with similar outcomes to RA, and hence why the M score for autoimmune disease as a whole is relatively low.

We found that – for 65% of the optimised recommendations analysed between 2015 and 2019 – the therapy was recommended for use in *less than half* of the potentially eligible population. Comparing our results with those calculated in previous research for an earlier time period (2006 – 2009), it can be seen that results are broadly in line but that for the more recent time period there are relatively fewer optimised appraisals with very low M score, as demonstrated in Table 2. For example, only 12.5% of the current sample had M scores below 10%, compared with over double this for the earlier time period.

TABLE 2 COMPARISON SUMMARY OF M SCORES WITH EARLIER ANALYSIS

	2006 – 2009 (O’Neill & Devlin, 2010)	2015 – 2020 (current analysis)
M>75 and ≤100	4 (12%)	4 (10%)
M>50 and ≤75	6 (17.5%)	10 (25%)
M>25 and ≤50	8 (23.5%)	12 (30%)
M≤25%	16 (47%)	14 (35%)
Total analysed	34	40
M≤50%	71%	65%
M≤10%	32%	12.5%

The analysis detailed in this report intends to throw some light on the levels of patient access associated with NICE optimised decisions. However, some limitations should be acknowledged. Of the 112 optimised recommendations considered, we were only able to calculate M for 40 of them. We have no way of knowing whether those in our sample are systematically different (in a way that would influence M) from those we were not able to include in our final sample due to lack of information. In addition, estimations cannot be precise, as interpretation is required in the calculation of M. The use of NICE's resource impact templates to inform the M score calculations means there was a single source of evidence, which reflects NICE's own view of patient eligibility from their guidance. These are also developed in cooperation with the company or companies sponsoring the medicines appraised. Whilst it would be possible to challenge the evidence used to inform each template, we have assumed that they are of reasonable quality. However, the aim of the resource impact templates is not to establish P and p, with the latter being the primary focus of the resource. Therefore, there was some ambiguity in matching the assumptions used in the template with the licensed indication. In some instances, these were readily apparent, but others required greater interpretation linking the description of the licence with a specific stage or stages in the template. This should be noted as an inherent limitation, which we attempted to reduce by excluding appraisals where P was ambiguous, by erring on the side of caution (in general assuming access was recommended) in cases where significant interpretation was required, and by having all M scores estimated by two analysts, with any disagreements discussed and agreed.

For this analysis, we only reviewed NICE 'optimised' recommendations. However, it should be noted that even for those decisions that are classified by NICE as 'recommended', these do not always imply 100% patient access relative to licence. Recommended decisions are actually of two types:

- In line with marketing authorisation from the EMA or MHRA
- In line with how it is used in clinical practice in the NHS

In an analysis performed by the OHE in 2016, we found that decisions that were recommended in line with clinical practice shared many characteristics with optimised decisions, both in terms of the evidence used to influence the recommendation level, as well as the level of patient access (M score) associated with the decision: an average of just 35% for the decisions reviewed (O'Neill et al., 2016).

Although speculative, we can estimate the level of patient access associated with NICE decisions overall by making some assumptions about access levels associated with each 'type' of recommendation. For example, between 2015 and 2019, there were 136 'recommended' decisions, 112 'optimised' recommendations, and 47 not recommended. If we assume that the M score is 39 for all optimised (the average identified in this report), 100 for recommended and 0 for not recommended, the overall M score for all TAs published between 2015 and 2019 would be 61; that is, 61% of potentially eligible patients across all TAs were recommended treatment. This is likely to be an overestimate given that recommendations include 'in line with clinical practice', which previous research has shown to be associated with lower access scores, and also given some restrictions that may be applied by NHS England in their commissioning criteria.

5 Conclusion

The statement that 82% of NICE appraisal recommendations are positive is not reflective of the recommended level of patient access associated with those decisions. A significant portion of positive decisions by NICE are 'optimised' recommendations: 43% over the last 5 years. Of the 112 medicines that received an optimised decision between January 2015 and December 2019, 40 included sufficient information to calculate M. For approximately two-thirds of this sample, access to treatment was recommended for less than half of the eligible patient population. Whilst the justification for these restrictions may be well founded, more granular reporting of recommendations would help paint a more accurate picture of recommended levels of patient access associated with NICE decision outcomes.

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Appendix

TABLE A1: NUMBER OF NICE RECOMMENDATIONS BY YEAR ACCORDING TO DECISION OUTCOME

Year	Recommended	Optimised	Not Recommended	Recommended (CDF)	Optimised (CDF)	Only in Research	Terminated Appraisal – non submission	Total
2000	24	3	1	0	0	3	0	31
2001	25	7	6	0	0	2	0	40
2002	35	3	4	0	0	7	0	49
2003	16	9	1	0	0	2	0	28
2004	43	8	0	0	0	0	0	51
2005	18	4	1	0	0	5	0	28
2006	22	8	2	0	0	1	0	33
2007	18	5	7	0	0	0	0	30
2008	21	17	10	0	0	1	4	53
2009	16	1	8	0	0	1	1	27
2010	20	17	8	0	0	2	3	50
2011	20	5	11	0	0	0	3	39
2012	22	1	12	0	0	1	1	37
2013	15	9	9	0	0	1	6	40
2014	24	4	3	0	0	0	1	32
2015	27	14	8	0	0	0	6	55
2016	37	26	10	1	0	0	1	75
2017	24	40	15	8	2	1	12	102
2018	32	13	9	6	4	1	2	67
2019	16	19	5	11	2	0	12	65

Data obtained from NICE (2020a)



About us

Founded in 1962 by the Association of the British Pharmaceutical Society, the Office of Health Economics (OHE) is not only the world's oldest health economics research group, but also one of the most prestigious and influential.

OHE provides market-leading insights and in-depth analyses into health economics & health policy. Our pioneering work informs health care and pharmaceutical decision-making across the globe, enabling clients to think differently and to find alternative solutions to the industry's most complex problems.

Our mission is to guide and inform the healthcare industry through today's era of unprecedented change and evolution. We are dedicated to helping policy makers and the pharmaceutical industry make better decisions that ultimately benefit patients, the industry and society as a whole.

OHE. For better healthcare decisions.

Areas of expertise

- Evaluation of health care policy
- The economics of health care systems
- Health technology assessment (HTA) methodology and approaches
- HTA's impact on decision making, health care spending and the delivery of care
- Pricing and reimbursement for biologics and pharmaceuticals, including value-based pricing, risk sharing and biosimilars market competition
- The costs of treating, or failing to treat, specific diseases and conditions
- Drivers of, and incentives for, the uptake of pharmaceuticals and prescription medicines
- Competition and incentives for improving the quality and efficiency of health care
- Incentives, disincentives, regulation and the costs of R&D for pharmaceuticals and innovation in medicine
- Capturing preferences using patient-reported outcomes measures (PROMs) and time trade-off (TTO) methodology
- Roles of the private and charity sectors in health care and research
- Health and health care statistics

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