HTA199

Increased trends of self-optimised submissions to NICE

Ask us about your favourite submission!

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Objectives

The objective of this poster is to demonstrate the trends associated with the self-optimised submissions to NICE. An optimised submission is one where the technology appraisal guidance recommends the treatment "only if", a certain set of criteria are met, that restrict the use of the treatment relative to its marketing authorisation. In this research, self-optimised criteria denotes company-initiated usage restrictions such as subgroup narrowing, treatment sequencing and stopping rules. Self-optimisation does not include aligning to NICE HTA appraisals and/or relevant clinical guidelines. This research builds on the Darrow et al. (2025) analysis of NICE's optimised decisions from 2015 to 2024. It quantified size of the patient groups that missed out on the novel treatments as a result of optimised recommendations which were narrower than the marketing authorisation. The research aim is to increase understanding of trades offs made during the pre-launch strategy development for new treatments, and reimbursement decisions led by NICE.

Methods

The public TACrawlR database was examined for all NICE optimised recommendations, published from 01/01/2015 to 31/05/2025. Microsoft Copilot® was initially used to classify whether each submission was self-optimised based on the final draft guidance and committee papers using the prespecified criteria (outlined in the objectives). Those outputs were validated by two Market access specialists. An independent, blinded team reviewed the verdicts about which party decided to optimise the final recommendations in ~10% of the sample. The independent team concluded that 23/24 (95.83%) decisions were correct. Table 1 described how the same type of restrictions could have either originated from the company or NICE.

Table 1: Same restrictions from different perspectives – TA examples

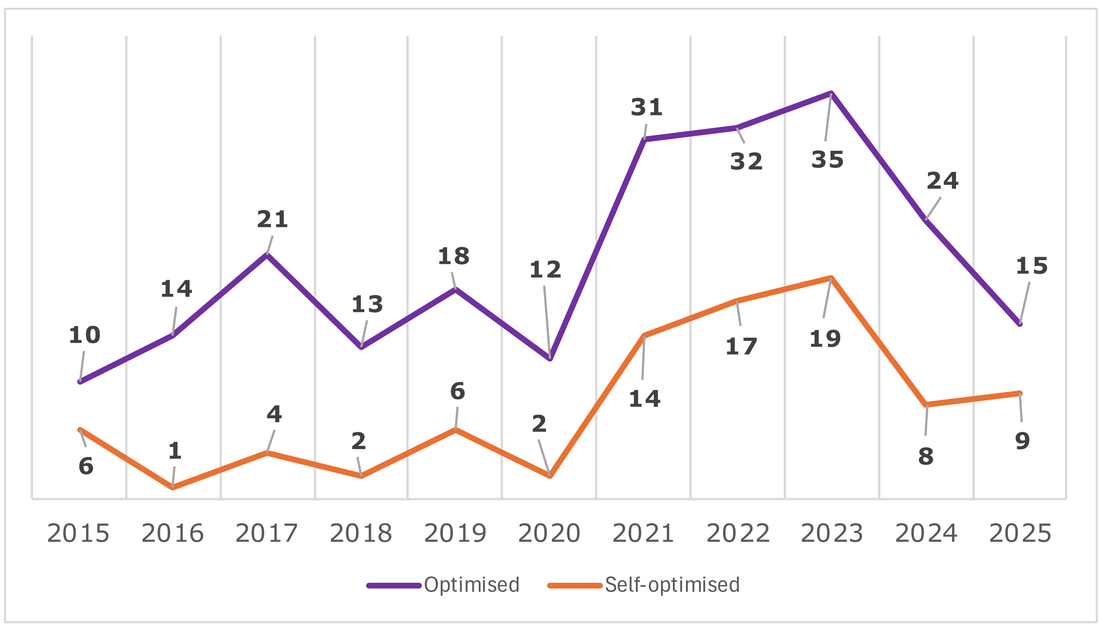
TA	Marketing authorisation	NICE optimisation	Type of optimisation
1050	Fenfluramine is indicated for 'the treatment of seizures associated with LGS as an add-on therapy to other antiepileptic medicines for patients 2 years of age and older'	If the frequency of drop seizures is checked every 6 months, and fenfluramine is stopped if the frequency is not reduced by at least 30% compared with the 6 months before starting treatment	Efficacy based continuation rule (**self-optimised**)
875	Semaglutide is 'indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI) of ≥30 kg/m² (obesity), or ≥27 kg/m² to <30 kg/m² (overweight) in the presence of at least one weight-related comorbidity'	If it is used for a maximum of 2 years, and within a specialist weight management service providing multidisciplinary management of overweight or obesity (including but not limited to tiers 3 and 4), and they have at least 1 weight-related comorbidity and: a body mass index (BMI) of at least 35.0 kg/m², or a BMI of 30.0 kg/m² to 34.9 kg/m² and meet the criteria for referral to specialist overweight and obesity management services in NICE's guideline on overweight and obesity management.	Duration based continuation rule (**not** self-optimised) and alignment to NICE's guideline on overweight and obesity management (**not** self-optimised)
791	Romosozumab is indicated for 'the treatment of severe osteoporosis in postmenopausal women at high risk of fracture'.	If they have had a major osteoporotic fracture (spine, hip, forearm or humerus fracture) within 24 months (so are at imminent risk of another fracture)	Company initiated subgroup restriction (**self-optimised**)
784	Niraparib has a marketing authorisation for 'the maintenance treatment of adult patients with platinum-sensitive relapsed high-grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy'.	If they have a BRCA mutation and have had 2 courses of platinum-based chemotherapy, or they do not have a BRCA mutation and have had 2 or more courses of platinum-based chemotherapy	NICE initiated subgroup restriction (**not** self-optimised)
758	Solriamfetol has a marketing authorisation 'to improve wakefulness and reduce excessive daytime sleepiness in adult patients with narcolepsy (with or without cataplexy)'.	If modafinil and either dexamfetamine or methylphenidate have not worked well enough or are not suitable.	Company initiated sequencing in terms of lines of treatment (**self-optimised**)
502	Ibrutinib inhibits a protein called Bruton's tyrosine kinase, stopping B-cell (lymphocyte) proliferation and promoting cell death.	If they have had only 1 previous line of therapy	NICE initiated sequencing in terms of lines of treatment (**not** self-optimised)

Results

The TACrawlR database reported 671 positive recommendations during the analysis period, with 302 optimised submissions. After filtering out the unique TA numbers (MTAs, replaced, and withdrawn appraisals) 223 optimised submissions were included in the final analysis. Figure 1 illustrates the number of optimised and self-optimised submissions over time. During 2015 the highest proportion of self-optimised submissions were observed (60%), while 2016 had the lowest (7%). Since 2016, the proportion has shown an upward trend. Notably, the years 2021 to 2023 saw substantial increase in both the total number of submissions and the number of self-optimisations. The analysis period ended in May 2025, accounting for the lower number of submissions recorded that year.

Determining the causal impact of self-optimisation remains challenging due to both external and internal factors. The proportion of self-optimised submissions has averaged 49% during the post-COVID years (2021–2025), with a range of 33% to 60%, but no significant shifts were observed that could be directly linked to NICE methods changes in 2022. Figure 2 presents a linear trendline, indicating an average annual increase of 5.25% in self-optimised submissions.

Figure 1: Optimised and self-optimised submissions (2015 - May 2025)



Conclusion

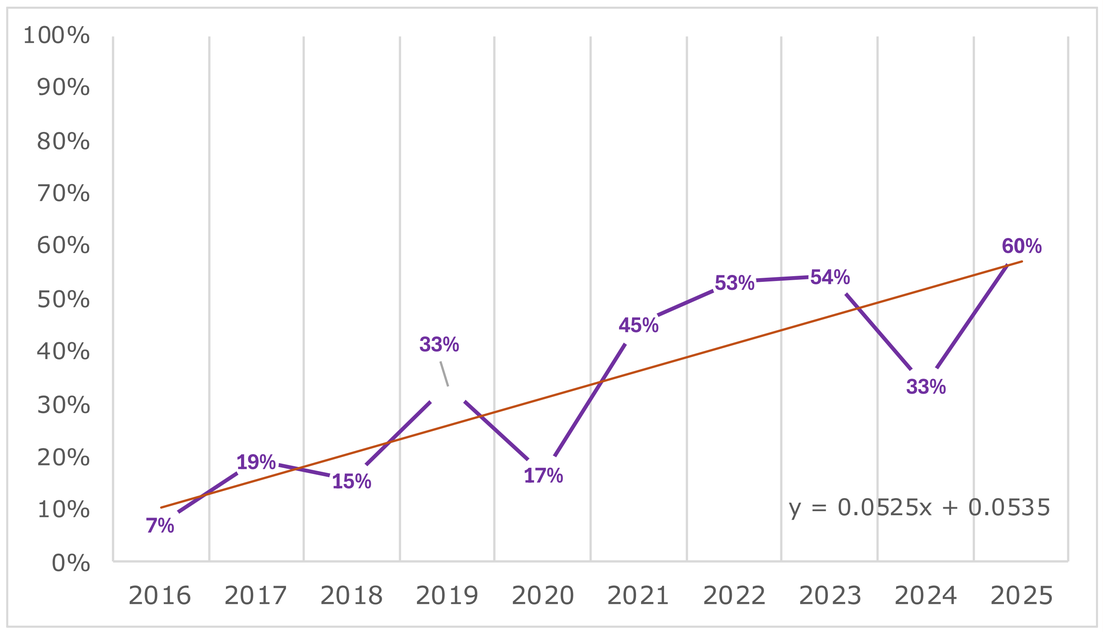
There is a clear upward trend of the proportion of optimised submissions that are self-optimised, indicating companies are increasingly proposing reimbursement for populations narrower than the marketing authorisation. A naïve extrapolation suggests that by 2033, all optimised recommendations could be company-initiated, pointing to an increasingly targeted reimbursement landscape.

Key research strengths include coverage of more than a decade of NICE submissions, yielding a large and diverse sample and the use of robust, well-specified definitions that enabled consistent categorisation in most cases.

Limitations stem from reliance on publicly available sources: the internal decision-making of companies and the committees' closed-session deliberations are not observable. Consequently, trade-offs between price and patient access cannot be inferred reliably across submissions and are likely heterogeneous, even within the same disease areas.

While this study quantifies macro-level trends, future work should examine micro-level dynamics within individual disease areas to understand how specific factors have shaped the evolution of reimbursement over time.

Figure 2: Percentage of self-optimised submissions (ex. 2015)



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References:

1. Darrow B., Chowdhury S., O'Neill P., Henderson N. , An Analysis of NICE's Optimised Decisions from 2015 to 2024 (2025). Contract Research.
2. National Institute for Health and Care Excellence (NICE) (2025) Fenfluramine for treating seizures associated with Lennox–Gastaut syndrome in people 2 years and over.
3. NICE (2023) Semaglutide for managing overweight and obesity
4. NICE (2022) Romosozumab for treating severe osteoporosis
5. NICE (2022) Niraparib for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer
6. NICE (2022) Solriamfetol for treating excessive daytime sleepiness caused by narcolepsy
7. NICE (2018) Ibrutinib for treating relapsed or refractory mantle cell lymphoma

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#Research simplified the parties to in the optimisation process to the company and NICE, although the term 'NICE' encompasses the wider stakeholder group such as