AN ASSESSMENT OF THE APPLICATION OF THE NICE SEVERITY MODIFIER

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Introduction

In January 2022, the National Institute for Health and Care Excellence (NICE) introduced a severity modifier weighting replacing the end-of-life (EOL) criteria.

The EOL criteria was previously used to assess the benefits of treatments for diseases associated with a short life expectancy.

The EOL criteria applied to treatments for patients with a life expectancy less than 24 months offering an extension to life of at least three months compared to the current standard of care.

If the criteria was met, the cost-effectiveness threshold was increased to £50,000 per quality-adjusted life year (QALY) gained.[1]

The severity modifier is intended to broaden the concept of 'severity' from short life expectancy exclusively.

If a company demonstrates a specified level of severity for the indicated population, a weight of 1.2 or 1.7 is applied to the QALYs, effectively raising the cost-effectiveness threshold to £36,000 or £51,000, respectively.

The level of severity is demonstrated through meeting either an absolute or a proportional QALY shortfall threshold.

Objective

To assess the application of the severity modifier compared to the EOL criteria.

Method

All documentation relating to eligible technology appraisals (TAs) was accessed from the NICE website (21st June 2024).

Eligibility was defined as an appraisal having a final scope dated after January 31st, 2022, and a published technology appraisal guidance.

The term 'severity modifier' was searched for in all documents. If not mentioned, it was assumed that the company did not apply to use a severity modifier weighting.

The remaining TAs were screened to determine if the company calculated the QALY shortfall, whether the thresholds were met, and whether the committee accepted the resulting severity modifier weighting.

The remaining TAs were screened to assess whether the submitting company claimed that they would have met the EOL criteria, and if so, the severity modifier outcome.

Results

Overview of eligible TAs

A total of 84 TAs met the eligibility criteria. Of those, 35 (42%) estimated QALY shortfall and applied resulting severity modifiers.

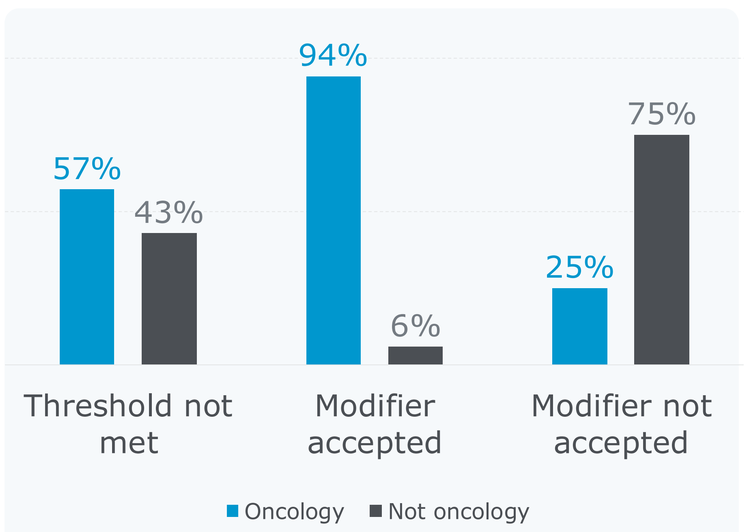
The outcome for the 35 TAs were as follows:

- **14 (40%)** did not meet any of the QALY shortfall thresholds and consequentially did not submit a severity modifier.
- **4 (11%)** submitted with severity modifier but modifiers were rejected by NICE.
- **4 (11%)** severity modifier of 1.7 accepted by NICE.
- **11 (31%)** severity modifier of 1.2 accepted by NICE.
- **2 (6%)** severity modifiers of both 1.7 and 1.2 (corresponding to different comparators) accepted by NICE.
- **In total, 17 (49%)** of the TAs which submitted with a severity modifier had the modifier approved.

Outcomes per type of indication

All except one of the indications for which the severity modifier was approved were in oncology. The exception was chronic hepatitis D, which reached a 1.2 severity modifier. **Table 1** lists the outcomes by indication.

Figure 1: Outcomes of severity modifier assessment split by oncological and non-oncological indications



Comparison to EOL criteria

In 3 (9%) of the 35 eligible TAs, the submitting company claimed that they would have met the EOL criteria. One achieved a severity modifier of 1.7 (multiple myeloma), one 1.2 (adenocarcinoma) and one achieved both 1.7 and 1.2 (endometrial, biliary, colorectal, gastric or small intestine cancer).

In addition, 4 (11%) were TA updates, all which had previously met the EOL criteria. One achieved a severity modifier of 1.2 (thyroid cancer), one of 1.7 (acute lymphoblastic leukaemia) and two did not calculate a severity modifier.

Table 1: Severity modifier outcomes by indication

SM outcome	N	Indication
Not approved	1	Chronic graft-versus-host disease
	1	Haemolytic anaemia
	1	Renal cell carcinoma
	1	Ulcerative colitis
Threshold not met	3	Multiple myeloma
	1	Acute myeloid leukaemia
	1	Chronic heart failure
	1	COVID-19
	1	Endometrial cancer
	1	Follicular lymphoma
	1	Long-term insomnia
	1	Metastatic melanoma
	1	Migraine
	1	NSCLC
	1	Parkinson's
	1	Pompe disease
Approved: 1.7	1	Acute lymphoblastic leukaemia
	1	Cholangiocarcinoma
	1	Metastatic colorectal cancer
	1	Multiple myeloma
Approved: 1.2	3	Diffuse large B-cell lymphoma
	2	Breast cancer
	1	Biliary tract cancer
	1	Chronic hepatitis D
	1	Gastric cancer
	1	Hodgkin lymphoma
	1	NSCLC
	1	Thyroid cancer
Approved: 1.2† and 1.7§	1	Endometrial,† biliary,§ colorectal,† gastric§ or small intestine cancer§
	1	HGG,§ LGG†

HGG – High-grade glioma; LGG – Low-grade glioma; NSCLC – non-small-cell lung cancer.

Conclusions

- To date, the severity modifier has almost exclusively been applied to treatments in oncology indications, suggesting that chronic and otherwise severe indications with longer life expectancy have not benefitted as intended by NICE.
- While data are limited, treatments which would have met EOL criteria and been assessed at a cost-effectiveness threshold of £50,000 may be disfavoured under the severity modifier – meeting only the lower severity threshold (corresponding to a £36,000 cost-effectiveness threshold) or not meeting a threshold of 'severe' at all.
- It is unclear if applications to NICE following the introduction of the severity modifier have reduced or increased. To be able to assess the success of the introduction of the severity modifier further, studies to assess the absolute number of appraisals that met a higher cost-effectiveness threshold, before and after the introduction of the new methods, are required.

Want to know more?

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References: 1. NICE health technology evaluations: the manual. https://www.nice.org.uk/process/pmg36/chapter/committee-recommendations-2 Accessed 28th October 2024