NICE Severity Modifier: what we have learned so far

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Introduction

In February 2022, the National Institute for Health and Care Excellence (NICE) introduced a quality-adjusted life year (QALY) severity modifier that aimed to give more weight to the health benefits of technologies for the most severe conditions.[1]
Two measures of severity were introduced based on the QALYs lost (Figure 1). Absolute shortfall would be expected to cover severe, chronic diseases that impact younger populations. Conversely, a proportional shortfall may be expected to impact older populations that would typically have fewer QALYs remaining without the disease.[2]
Like the previous end-of-life criteria, the QALY modifier aims to aid the evaluation of eligible technologies by making it easier to be within the range considered cost-effective (Table 1, Figure 2).
By considering both the quality and quantity of life lost, as well as QALYs lost over a prolonged period of time, the severity modifier should allow a greater range of conditions to be eligible than the previous end-of-life modifier, thereby facilitating patient access to treatments for the most severe diseases.

Figure 1: Definitions of severity

$$\text{Absolute shortfall} = \text{Total QALYs lost due to the disease}$$

$$\text{Proportional shortfall} = \frac{\text{Total QALYs lost due to the disease}}{\text{QALYs a patient would have without the disease}}$$

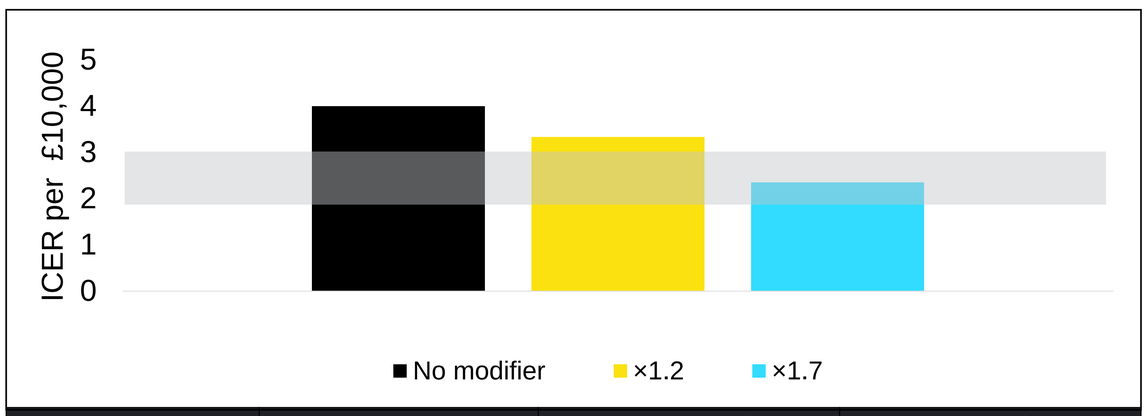
QALY, quality-adjusted life year

Table 1: Severity modifier criteria

Absolute QALY shortfall	Proportional QALY shortfall	QALY weight applied
Less than 12	Less than 0.85	No modifier applied
12 to 18	0.85 to 0.95	×1.2
At least 18	At least 0.95	×1.7

QALY, quality-adjusted life year

Figure 2: Hypothetical scenario of the impact of different modifiers



	Incremental costs	Incremental QALY	Incremental ICER
No modifier	£60,000	1.5	£40,000
×1.2		1.8	£33,333
×1.7		2.55	£23,529

Hypothetical situation where a new treatment presents with incremental costs of £60,000 and offers incremental 1.5 QALYs gained. The shaded grey bar presents the range at which NICE typically considers a product to be cost-effective. A substantial confidential discount to the price of the product would be required for NICE to recommend the product if no modifier was applied.

ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life year

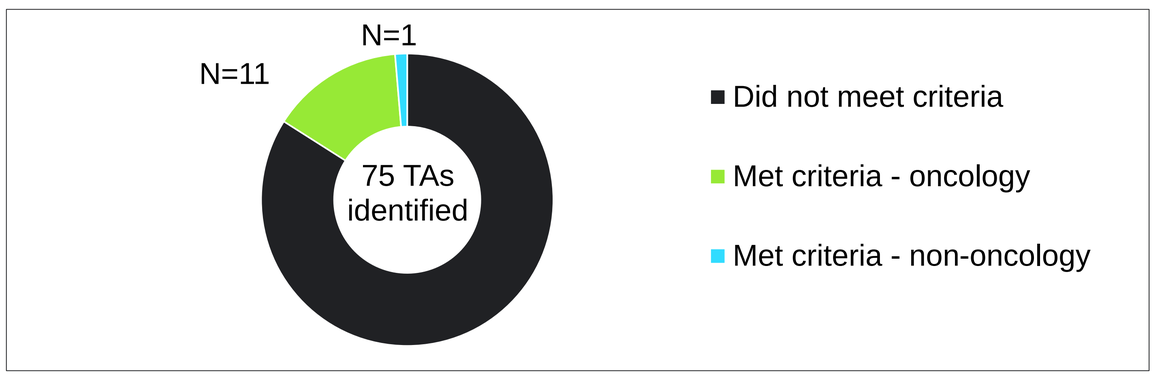
Methods

To determine the impact of the QALY modifier on health technology assessment outcomes and to understand which conditions have benefited, we evaluated recent NICE technology assessment reports from December 2022 (the date of the first published assessment including a severity modifier) to April 2024.
Appraisal reports were screened for information regarding the severity modifier applied. Terminated appraisals were not included in the analysis.

Results

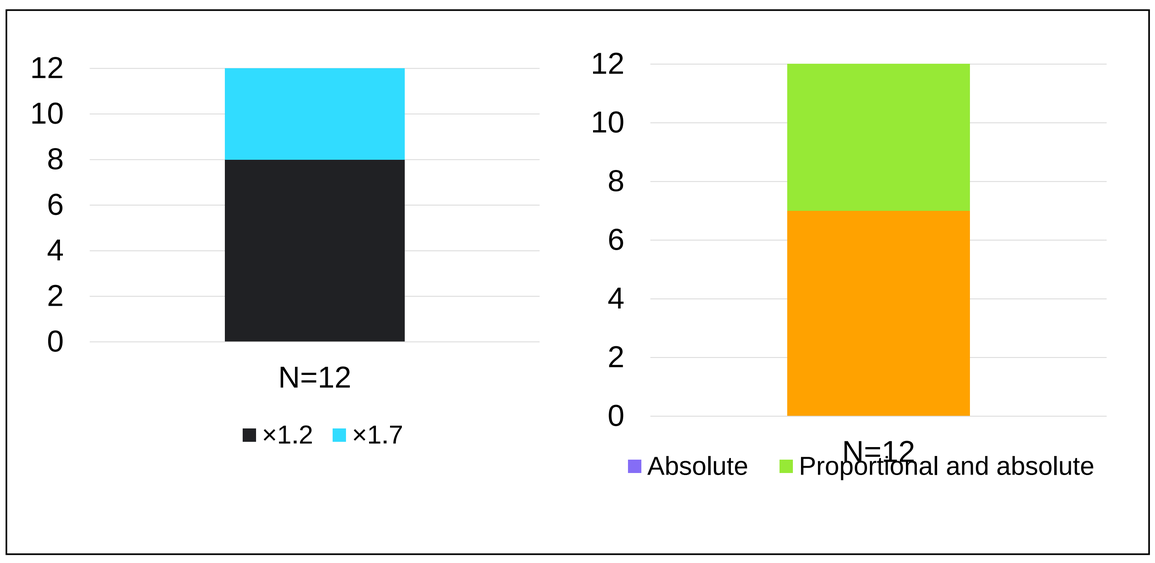
In total, 75 eligible technology assessments were identified on the NICE website.[3] Of these, only 12 met one of the severity criteria for a QALY modifier (Figure 3).
Of these, 11 were for oncology indications, and most (8/12) met the lower criteria for a modifier of ×1.2 to be applied (Figure 4).
In total, seven out of 12 technology assessments met the criteria based on the proportional QALY shortfall and five met both the proportional and absolute shortfall criteria. There were no assessments that met solely the absolute shortfall criteria (Figure 4).
Almost all technologies where a severity modifier was applied were recommended for reimbursement (11/12; two of these with a managed entry agreement).
There was a general agreement between the manufacturers and NICE on the QALY shortfalls (and consequently the modifier applied), with disagreement appearing in only one assessment.

Figure 3: NICE technology appraisals meeting the criteria for a severity modifier



TA, technology assessment

Figure 4: Breakdown of the criteria met



Conclusions

Most diseases appear to be not eligible for the severity modifier, and among those that do meet the criteria, most only qualify for the lower modifier, which will have only a minor impact on a product's incremental cost-effectiveness ratio.
Recent analyses suggested that fewer products meet the severity modifier than those which were previously benefiting under the end-of-life criteria, where 18% of assessments qualified, which equated to a modifier of approximately 1.7 (versus 2.5% of current assessments).[4]
Moreover, given that most of those meeting the criteria were oncology indications and doing so under the proportional shortfall criteria (indicative of an acute condition), it appears that the implementation of the modifier has not broadened the range of diseases benefiting as intended.
Together, the implementation of the severity modifier has in effect reduced the number of acute life-threatening conditions that would likely meet the threshold for most severe diseases, without fully allowing to more chronic conditions to benefit. For manufacturers, this may lead to additional price pressure to successfully enter the UK market.

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