HTA11

A NICE Idea? Assessing the Impact of the Severity Modifier in Oncology and Non-Oncology Single Technology Appraisals

Disclosures: The report was authored by Charles River Associates ("CRA"). The conclusions set forth in this report are based on independent research and publicly available material. The views expressed in this report are the views and opinions of the authors and do not necessarily reflect or represent the views of CRA.

Introduction

In February 2022, NICE replaced the End Of Life (EOL) modifier with the 'Severity Modifier', in part to address criticism that EOL criteria were too narrow

- It aims to capture disease burden **beyond cancer patients with short life expectancies** to broaden access to innovative treatments
- There are **potential QALY weightings of 1.2x or 1.7x** based on severity, measured by absolute and proportional QALY shortfalls
- It was also **designed to maintain opportunity cost neutrality** with previous EOL criteria

Table 1. Severity modifier weightings and QALY shortfall thresholds

QALY multiplier (CE threshold upper limit in '000s)	x1 (£30k)	x1.2 (£36k)	x1.7 (£50k)
Absolute QALY shortfall	<12	12 to 18	> 18
Proportional QALY shortfall	<0.85	0.85 to 0.95	> 0.95

Objectives

1. **Explore the application and impact of the Severity Modifier** since its implementation in 2022
2. Explore **differences in the application of the Severity Modifier between Oncology & Non-Oncology treatments**, to identify if the Severity Modifier has supported ICER flexibility for non-Oncology conditions

Methods

CRA analysed all NICE STAs since the introduction of the Severity Modifier in February 2022 to March 2025 (n=290)

Methodology

- Published NICE recommendations and committee discussion notes were reviewed for each STA
- All STAs were analysed by two researchers independently & disagreements reviewed by a third reviewer

Data Extracted

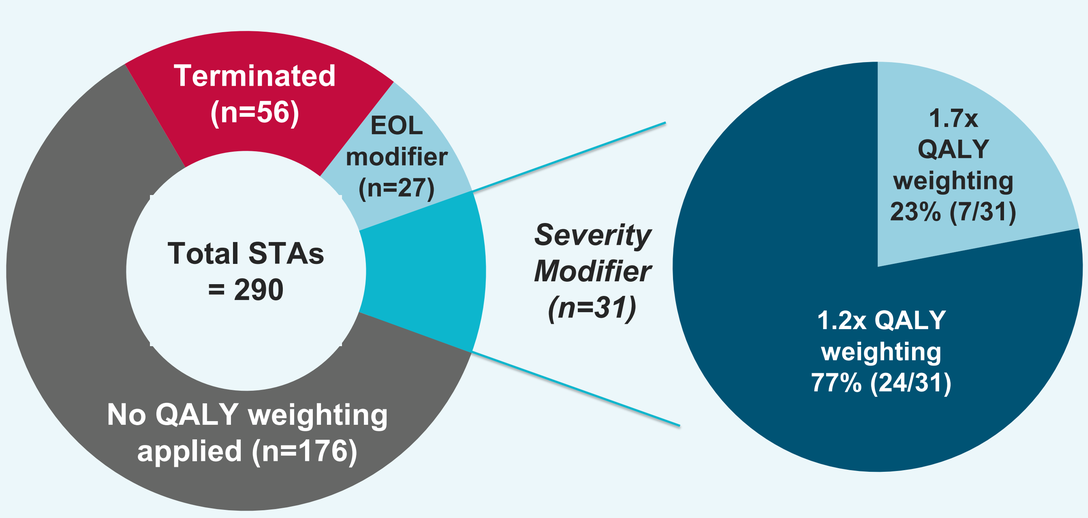
- Therapeutic area
- Discussion & application of the Severity Modifier
- QALY weighting applied for Severity Modifier (if applied)
- Remaining use of EOL

Results: *How has the Severity Modifier been applied, and is there a difference for Oncology?*

Breakdown of Application of the Severity Modifier

Figure 1. Breakdown of NICE STAs by applied QALY weighting

Figure 2. Distribution of applied Severity Modifier QALY weightings



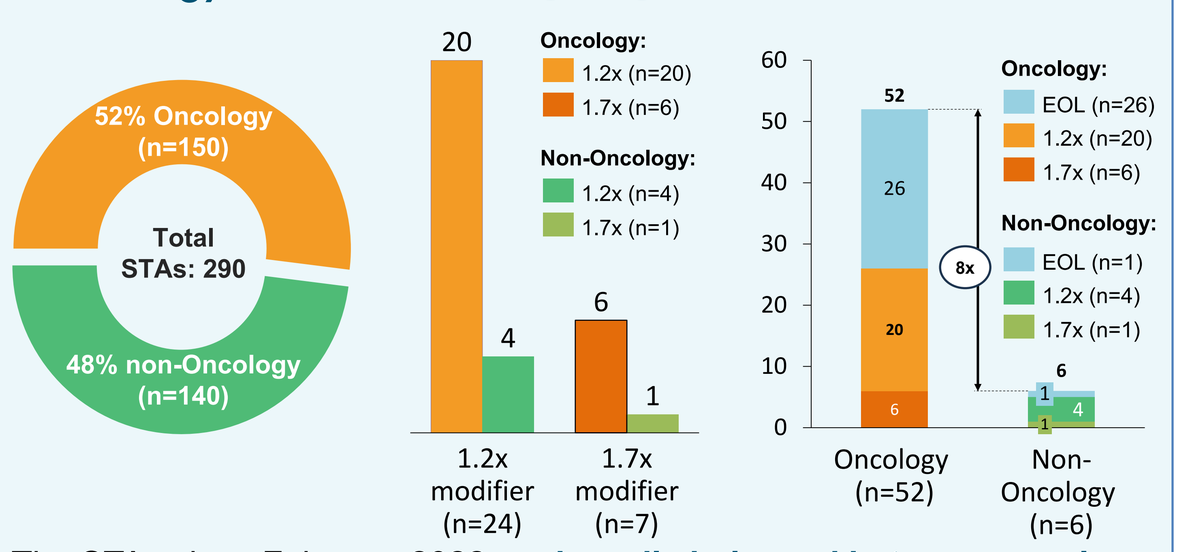
- In line with expectations, **no QALY weighting was applied to the majority of completed STAs (61%)** *(Figure 1)*
- **11% (31/290) of STAs were awarded a Severity Modifier whereas 9% (27/290) were awarded the EOL modifier** (due to evidence submitted prior to introduction of the Severity Modifier in 2022) *(Figure 1)*
- The lower **1.2x Severity Modifier was applied in the vast majority of cases (77%, 24/31)**; whereas **only 23% (7/31) products achieved the 1.7x Severity Modifier** and access to the £50,000 ICER *(Figure 2)*

Comparing Oncology vs. Non-Oncology treatments

Figure 3. Split of oncology & non-oncology STAs

Figure 4. Appraisals with1.2x or 1.7x weighting

Figure 5. Total modifiers awarded since Feb. 22



- The STAs since February 2022 are **broadly balanced between oncology (52% n=150) and non-oncology (48% n=140) indications** *(Figure 3)*
- QALY Severity Modifiers continue to be **predominantly awarded to oncology indications (84% 26/31)**; and **only 1 non-oncology product was awarded the highest Severity Modifier of 1.7x** *(Figure 4)*
- **Oncology appraisals are >5x more likely** to receive a Severity Modifier (26 oncology vs. 5 non-oncology), and **>8x more likely** to have received a QALY weighting when considering both Severity & EOL modifiers *(Figure 5)*

Key takeaways: *Areas for further discussion and analysis*

The Severity Modifier mainly benefits oncology products

- There is a continued **disproportionate benefit for oncology treatments;** only **1x non-oncology treatment was awarded the greatest Severity Modifier (1.7x)** over the 3 years since its introduction
- One **could argue there are fewer diseases as severe as oncology,** and hence, explaining the results observed; further analysis needed
- Another **factor could be that fewer severe diseases were appraised during this 3-year period**; this is an area for further analysis

Achieving a £50k ICER is harder with the Severity Modifier vs. EOL

- The prior **EOL criteria were simpler** and focused on people who had limited time to live
- The Severity Modifier is **based on defined calculations and stricter criteria**
- The Severity Modifier has **reduced the number of oncology treatments achieving the highest Severity Modifier (1.7x, £50k ICER)**
- Under the previous rules, **treatments awarded 1.2x may have qualified for the EOL modifier**

NICE thresholds are restrictive compared to other markets

- The Severity Modifier is step forward, but **further refinements are needed to ensure equitable access across indications**; many severe diseases may still be unable to benefit from the modifier unless the thresholds are further adjusted
- Interestingly, several markets offer severity modifiers, however, the **severity thresholds used in the UK are more restrictive than those applied elsewhere** in the world (e.g., notably the Netherlands and Norway)

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References: [1] NICE health technology evaluations: the manual, PMG36, 14 July 2025; [2] Published NICE STAs between February 2022 and March 2025

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