

CONCLUSIONS

The new severity modifier offers a broader definition of severity by introducing additional severity weights of 1.2x at a threshold of £36,000. This approach considers absolute and proportional quality-adjusted life year shortfall, representing an improvement over the previous End-of-Life (EOL) criteria. There is little evidence to suggest that the modifier (absolute shortfall, proportional shortfall, and willingness-to-pay) aligns with societal preferences. The National Institute for Health and Care Excellence and different countries have acknowledged the need for further refinement of the modifier at the global level. New severity modifier replaces the EOL criteria, as the results of this study indicate that technologies previously eligible for EOL criteria are unlikely to receive the same benefits under the new severity modifier.

INTRODUCTION

- Disease severity is a key consideration in health technology assessment (HTA).¹ In 2009, the National Institute for Health and Care Excellence (NICE) introduced guidance for end-of-life (EOL) treatments, allowing incremental cost-effectiveness ratios (ICERs) up to £50,000 per quality-adjusted life year (QALY) using a severity modifier.² However, the EOL criteria were criticized for being too narrow and for overlooking quality-of-life improvements¹
- In January 2022, NICE introduced a new “severity modifier” that replaces the EOL criteria with a broader severity modifier¹
- NICE’s new severity modifier considers two different but related measures of disease severity: absolute shortfall (AS) and proportional shortfall (PS)³.
- AS represents the number of future QALYs that are lost by people living with the disease, and PS represents the proportion of future QALYs that are lost by people living with the disease ¹
- The rresulting QALY shortfall determined which of the severity weights of x1, x1.2, or x1.7 will be applied

OBJECTIVE

- To investigate the impact on QALY weights and cost-effectiveness thresholds if the severity modifier were applied to past appraisal
- To compare the new severity modifier with EOL criteria and to understand the scope of the severity modifier on a global scale

METHODS

- We reviewed previous NICE HTAs to identify cases for which the maximum WTP threshold would have changed if current severity modifiers were applied
- We identified one example each for an increased and decreased price potential, respectively, if severity modifiers were applied i.e. technology appraisal (TA) 668 (Encorafenib plus cetuximab for metastatic colorectal cancer) and TA 854 (Esketamine nasal spray for treatment-resistant major depressive disorder)
- Data required to estimate the AS and PS were extracted from committee papers and guidance
- This data included the average age at diagnosis, the percentage of females in the patient group, and the QALY experienced by patients receiving both the new treatment and the current standard of care (SoC).
- The age and gender data of the population are summarized in **Table 1**, while the QALY calculation can be found in **Figure 1**

Table 1: QALY shortfall calculator data

TA	Mean Age	% Female	Discount Rate
TA668	61	48	3.5%
TA854	45	66	3.5%

- The AS and PS were estimated using a publicly accessible tool widely utilized by HTA agencies to quantify the QALY shortfall associated with different health conditions⁴
- Based on the calculated shortfall, conditions were classified into three severity levels, each linked to a specific QALY weight (1.0, 1.2, and 1.7) as shown in **Table 2**. The corresponding severity modifier was then applied to reflect the seriousness of the condition

Figure 1: AS and PS calculations

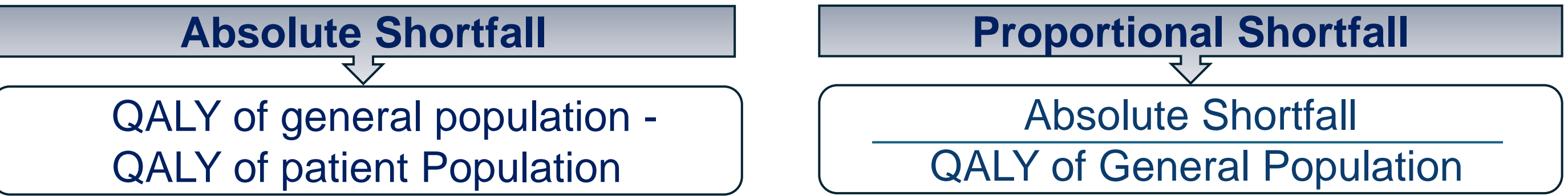


Table 2: QALY weight across AS and PS values

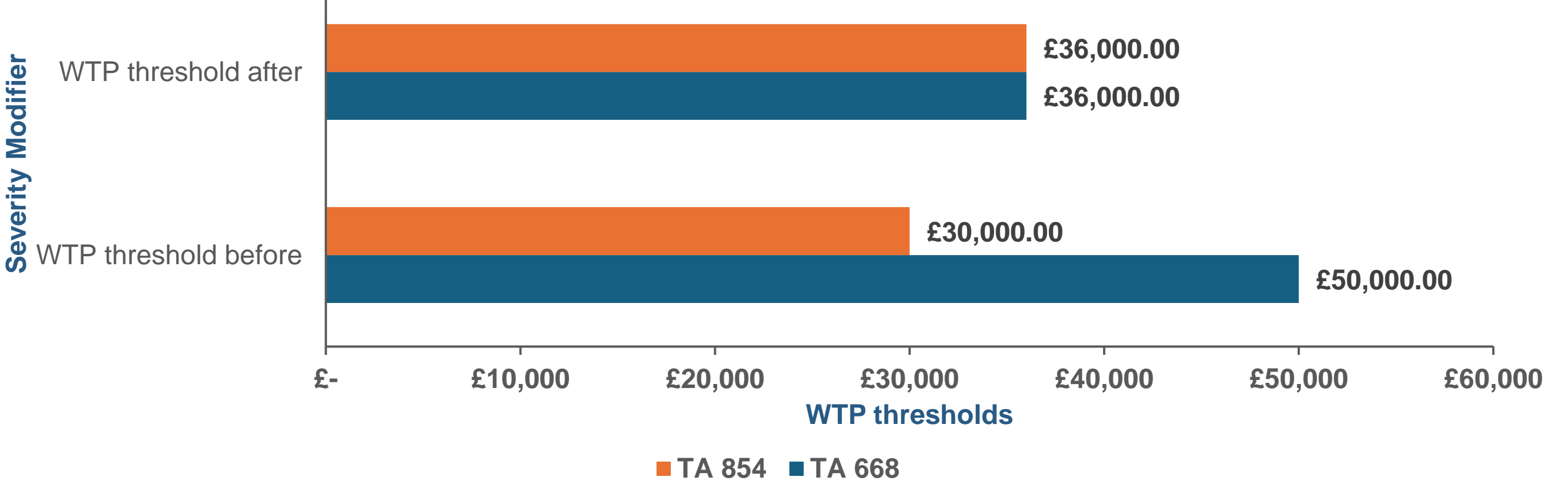
QALY Weight	AS	PS	WTP Threshold
x1	<12	<0.85	£20,000 to £30,000
x1.2	12 to 18	0.85 to 0.95	Up to £36,000
x1.7	≥18	≥0.95	Up to £51,000

AS: Absolute shortfall; PS: Proportional shortfall; QALY: Quality-adjusted life year

RESULTS

- The analysis identified two appraisals that illustrate contrasting impacts of the new severity multipliers on the willingness-to-pay (WTP) threshold.
- Detailed results, including statistical outputs generated using the shortfall calculator tool, are provided in **Table 3**, with the corresponding visual representations shown in **Figures 2** and **3**

Figure 2: WTP thresholds before and after applying the severity modifier

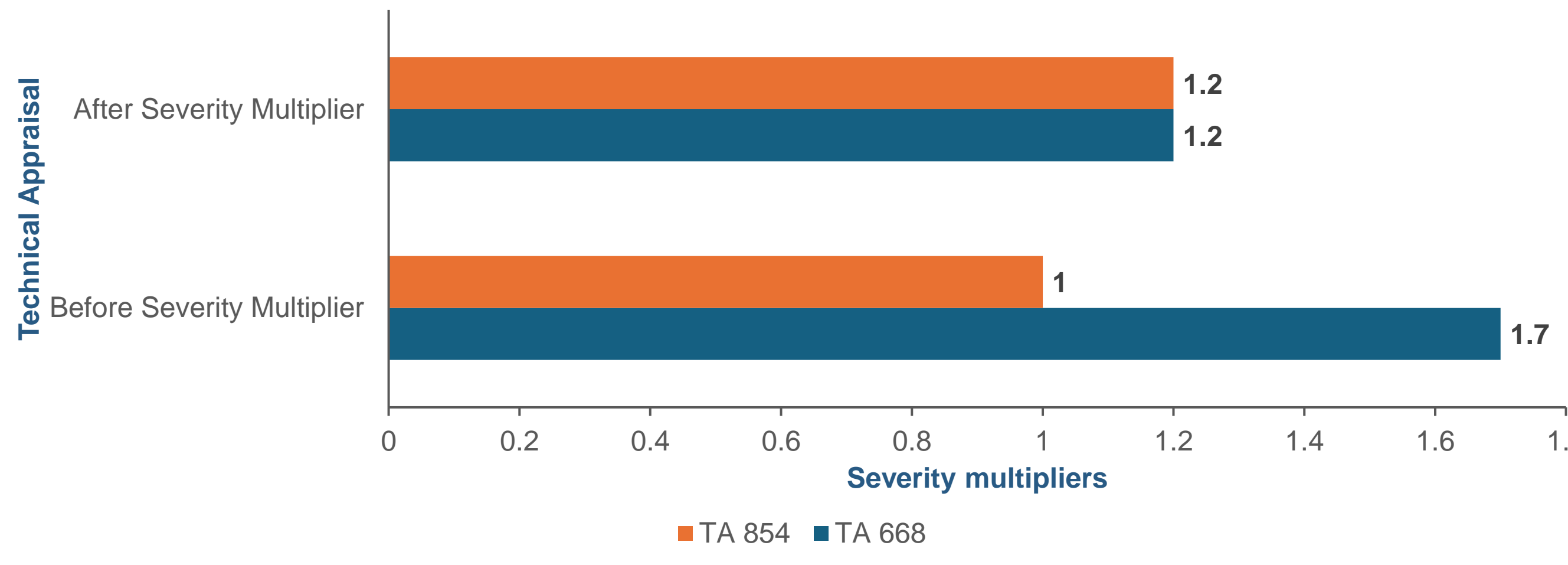


- Encorafenib plus cetuximab (TA668) as an option for treating BRAF V600E mutation-positive metastatic colorectal cancer in adults who have had previous systemic treatment

RESULTS (CONT'D)

- For the appraisal of Encorafenib plus cetuximab, the treatment met the established EOL criteria, which permits a WTP threshold of up to £50,000 per QALY. However, when the new severity multipliers were applied, the resulting WTP threshold was reduced to £36,000 as illustrated in Table 3
- Figure 2 shows variation in WTP thresholds in graphical form before and after applying the severity modifier across both TA

Figure 3: Severity Multiplier before and after applying the severity modifier



- In contrast, the appraisal of Esketamine nasal spray did not meet EOL criteria, limiting the WTP threshold to £30,000 per QALY; applying the new severity multipliers raised this to £36,000
- These findings highlight that severity multipliers can differentially impact WTP thresholds based on disease characteristics and treatment outcomes
- **Figure 3** illustrates the variation in the severity multiplier before and after applying the severity modifier across both TAs, providing a visual comparison of the impact on each appraisal

Table 3: Revisions to the WTP thresholds for the identified TAs

Previous TA	TA668	TA854
Previous WTP Thresholds	£50000	£36000
QALY without Disease	12.35	17.37
QALY with Disease	0.92	2.57
AS	11.43	14.8
PS	0.926	0.852
Severity Multiplier	1.2X	1.2X
Modified WTP threshold	£36000	£36000

TA: Technology appraisal; WTP: Willingness-to-pay

References

1. NICE's severity modifier: a step in the right direction, but still a long way to go - OHE [2023].
2. HTA73 Evaluation of NICE Severity Modifiers - Value in Health
3. Full list of technical support documents (TSDs) | NICE Decision Support Unit | The University of Sheffield: Technical Support Document NICE TSD 23
4. Available from: QALY Shortfall Calculator Schneider P, McNamara S, Love-Koh J, Doran T, Gutacker N. QALY shortfall calculator [Internet]. York, 2021 [cited 23 October

Sponsorship

This research is conducted solely by the authors without any collaboration from other institutes or pharmaceutical/biotech companies

Disclosures

PB, KP, AS, SK, and SP, the authors, declare that they haveno conflict of interest

Scan the QR code to save an offline version of poster

