A RETROSPECTIVE REVIEW OF NICE APPRAISALS FROM 2017-2022 TO INVESTIGATE THE IMPACT OF THE NEW SEVERITY MODIFIER ON COST-EFFECTIVENESS THRESHOLDS ACROSS MULTIPLE THERAPY AREAS

Katerina Christoforou[1], **Thomas McLean[1]**, Alex Herbert[1], Stamatia T. Alexopoulos[1]
[1]Merck Serono Ltd., Feltham, UK, an affiliate of Merck KGaA, Darmstadt, Germany

CONCLUSIONS

- **A review of all NICE single technology appraisals with unredacted data over the past 5 years has shown that only a small proportion of appraisals would have qualified for the highest severity modifier and therefore had a £50,000 cost-effectiveness threshold applied.**
- **The highest severity modifier was only applicable in oncology medicines, indicating a risk that a broader range of conditions may not benefit from the severity modifier.**
- **Only 16% of appraisals that qualified for end-of-life criteria would have qualified for the highest severity modifier, indicating a risk that the introduction of the severity modifier could reduce the number of appraisals that would have previously benefited from a higher cost-effectiveness threshold.**
- **Further research should be prioritised to inform future development and refinement of the severity modifier.**
- **This analysis is limited by a high proportion of NICE appraisals with redacted information.**

INTRODUCTION AND OBJECTIVES

Introduction

- The National Institute for Health and Care Excellence (NICE) recently published their new combined methods, process, and topic selection manual.[1]
- Part of this update includes the new severity modifier, which replaces the prior end-of-life criteria and is expected to apply to a broader range of conditions compared to the end-of-life criteria. [1]
- The severity modifier is based on two measures, the absolute and proportional quality-adjusted life year (QALY) shortfall. The resulting QALY shortfall will determine which of 3 severity levels is applied, with QALY weights of x1, x1.2 or x1.7. This, in turn will result in modified cost-effectiveness thresholds of £30,000, £36,000 and £50,000 by severity level, respectively.[1]
- However the impact the severity modifier will have in practice for future NICE appraisals is not known, particularly how many appraisals will qualify for each severity level.
- It is also not known how the new severity modifier will compare to the previous end-of-life criteria.

Objectives

- To investigate the impact on QALY weights and cost-effectiveness thresholds if the severity modifier was applied in past appraisals
- To understand how the application of the new severity modifier will vary by disease area
- To understand how the application of the new severity modifier compares to appraisals which previously qualified for end-of-life criteria

METHODS

- A targeted review of all NICE single technology appraisals (STAs) published on the NICE website in the last five years (June 2017 to May 2022) was conducted.
- All relevant information required to determine the QALY weight was extracted and documented from each appraisal (Table 1), where this was not redacted.
- The absolute and proportional QALY shortfalls were calculated to determine the QALY weight and severity level for each appraisal, using the ScHARR (University of Sheffield) calculator.[2]
- It was then determined which cost-effectiveness threshold would have been applied to each past NICE appraisal with the new severity modifier.

Table 1. Information extracted in review of NICE appraisals

Category	Extracted information
Disease and indication information	Indication, disease area, current standard of care, male/female ratio, average age at diagnosis
Model results	Discounted QALYs for SoC comparator
Other	If end-of-life criteria was applied

Key assumptions: (1) Data was extracted from the company submission; **(2)** Where multiple subgroups were included in the base case, the QALY weights were calculated for each and the lowest severity modifier assumed; **(3)** Where multiple comparators were included in the base case, the most relevant comparator was used or if not clear, the comparator with the lowest severity modifier assumed; **(4)** Where starting age or male/female ratio was redacted in the submission, pivotal trial data was used as a proxy; **(5)** Multiple technology appraisals were excluded (6) CDF reviews were considered as separate STA to original STA

RESULTS

Figure 1. Severity level and QALY weight that would have been applied to previous NICE appraisals (n=106)

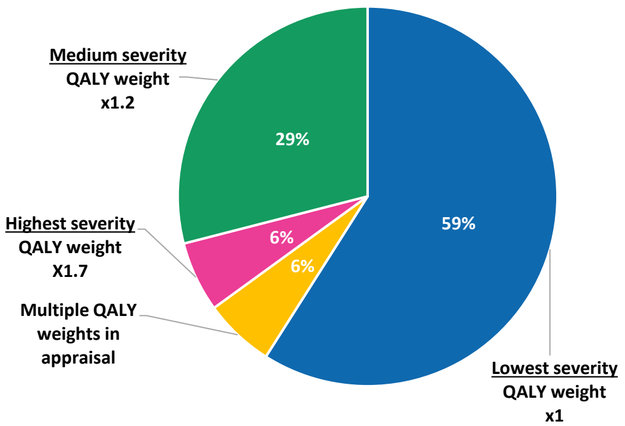
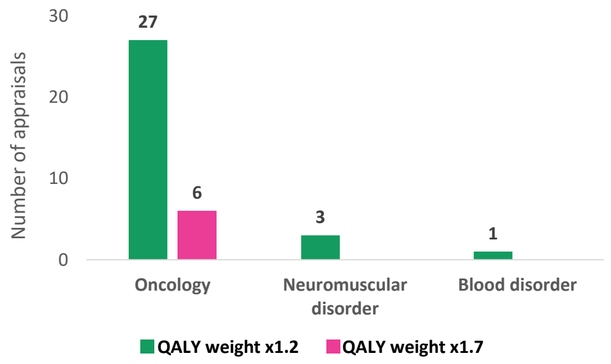
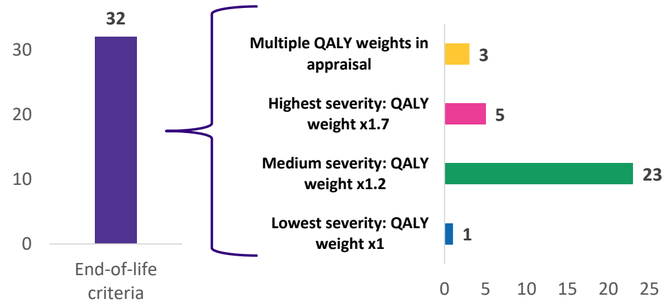


Figure 2. Disease areas included in appraisals with the x1.2 QALY weight (n=31) and x1.7 QALY weight (n=6)



- A total of 325 NICE STAs were reviewed, with 106 (33%) appraisals containing sufficient unredacted figures to be included in the analysis.
- Of the 106 unredacted appraisals, a QALY weight of x1 would have been applied to 63 (59%) appraisals, a QALY weight of x1.2 to 31 (29%) appraisals and a QALY weight of x1.7 to 6 (6%) appraisals (Fig 1).
- In 6 (6%) appraisals there were multiple QALY weights which would have been applied across subpopulations, which included 3 subpopulations with QALY weights of x1.7 and 5 subpopulations with QALY weights of x1.2.
- Of the 31 appraisals where a QALY weight of x1.2 would have been applied, 27 were in oncology indications, 3 were in neuromuscular disorders, and 1 was in a blood disorder (Fig 2). Of the appraisals with multiple QALY weights, the subpopulations with a x1.2 QALY weight were in oncology indications (n=3), a neuromuscular disorder (n=1) and an immunological disorder (n=1).
- Of the 6 appraisals where the highest severity level would have been applied, all were in oncology (Fig 2). Of the appraisals with multiple QALY weights, the subpopulations with x1.7 QALY weight were also all in oncology (n=2).
- 32/106 appraisals identified qualified for end-of-life criteria. If the severity modifier had been applied, 5 appraisals would have had a x1.7, 23 would have had a x1.2, and 1 would have had a x1 QALY weight, respectively. The other 3 would have had a mix of QALY weights across subpopulations (Fig 3).
- In 1 appraisal which did not qualify for end-of-life criteria, a x1.7 QALY weight would have been applied.

Figure 3. Severity level and QALY weights which would have applied in appraisals with end-of-life criteria applied (n=32)



Abbreviations: NICE; The National Institute for Health and Care Excellence, QALY; Quality-adjusted life year, ScHARR; School of Health and Related Research, SoC; standard of care.

References: 1. NICE methods and process 2022. https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation. Accessed September 2022. 2. ScHARR QALY Shortfall calculator. https://r4scharr.shinyapps.io/shortfall/. Accessed September 2022.

Disclosures: TM, KC, AH, SA are employees of Merck Serono Ltd, Feltham, UK, an affiliate of Merck KGaA, Darmstadt, Germany. This research was financially supported by Merck Serono Ltd., Feltham, UK, an affiliate of Merck KGaA (CrossRef Funder ID: 10.13039/100009945)

Abstract No. 121312. Poster HTA64. Presented at ISPOR Europe 2022, Vienna, Austria and Virtual, November 6-9, 2022