How has NICE's severity modifier been implemented?

HTA122

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INTRODUCTION AND OBJECTIVE

- In January 2022, the National Institute for Health and Care Excellence (NICE) published its updated manual on methods and processes for health technology evaluations. As part of this update, NICE introduced a quantitative decision modifier based on disease severity[1]
- NICE defines disease severity as the future health lost by people living with the condition having standard care in the NHS. This is assessed through absolute and proportional quality-adjusted life year (QALY) shortfall, as defined below:
  - ↳Absolute shortfall: difference between potential future QALYs and QALYs with current standard of care (i.e. Areas A+B+C+D minus area D in Figure 1)[1,2]
  - ↳Proportional shortfall: ratio of QALYs lost over the QALYs remaining (i.e., Areas A+B+C as a proportion of Areas A+B+C+D in Figure 1)[1,2]
- For conditions that qualify for the severity modifier, a QALY weight of 1.2 to 1.7 is applied, depending on the shortfall (Table 1)
- This study aims to understand how the severity modifier has been implemented so far and its impact on committee decision making

Figure 1. Overview of QALYs taken into account for proportional and absolute shortfall calculations (adapted from OHE[2])

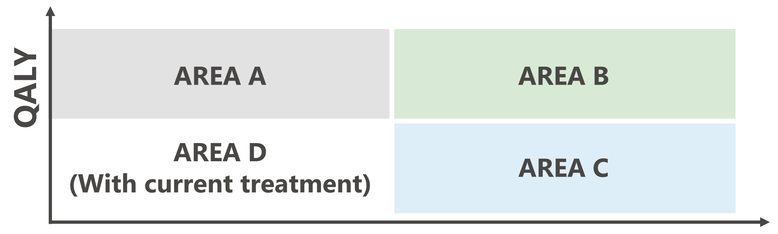

Table 1. QALY weightings for severity[1]

QALY WEIGHT	PROPORTIONAL QALY SHORTFALL	ABSOLUTE QALY SHORTFALL
1	Less than 0.85	Less than 12
x1.2	0.85 to 0.95	12 to 18
x1.7	At least 0.95	At least 18

METHODS

- NICE health technology evaluations for which the updated methods applied (with final scopes from February 2022 onwards, cut-off date July 2023), were identified from publicly available information. As the severity modifier does not apply to the highly specialised technologies (HST) process, only topics undergoing NICE's single technology evaluation process were identified
- Evaluation documents were analysed to collect data on indication, cost-effectiveness results, recommendations, and mention of the severity modifier
  - For relevant evaluations, details on the company's approach to the severity modifier, NICE's critique of the severity modifier and the impact on the outcome of the appraisal were assessed

RESULTS

- 27 relevant evaluations were identified with draft or final guidance. The company made the case for the severity modifier in 3 evaluations: TA862, TA866, TA896 (Table 2)
- Of these 3 appraisals, a severity weighting was applied by the NICE committee in only 2, including a 1.2 weighting in TA896 and a 1.7 weighting to a subgroup in TA866. Both these technologies were recommended for use in routine commissioning. In contrast, the NICE committee concluded that there was high uncertainty on severity being met in TA862. The technology (trastuzumab deruxtecan) was recommended for use only within the Cancer Drugs Fund
- Unlike TA862 and TA866, TA896 was for a non-cancer therapy area and had a relatively young patient population. In each of the 3 appraisals, the manufacturer used the online Schneider tool to calculate proportional and absolute shortfall

Figure 2. Overview of number of company submission including a case for the severity modifier

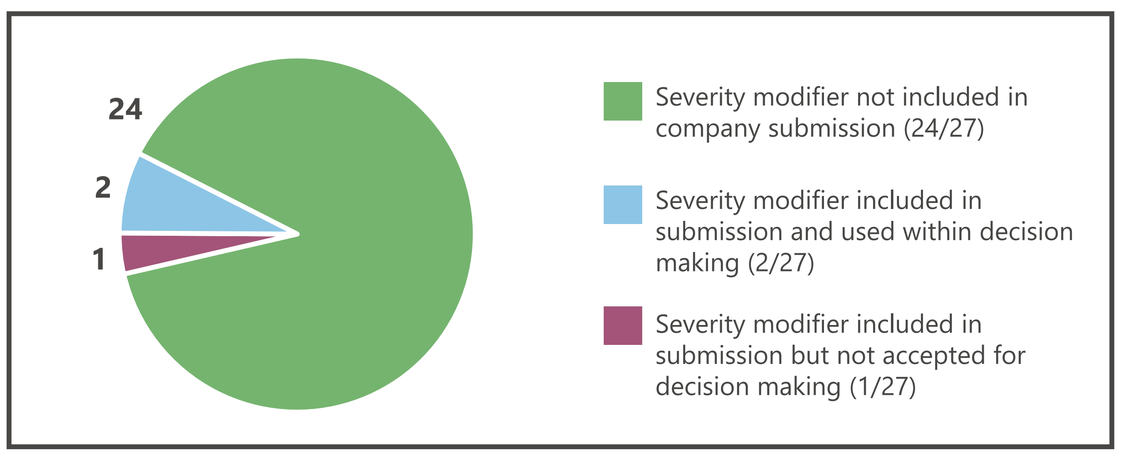

Table 2. Overview of appraisals including a case for the severity modifier

APPRAISAL	INTERVENTION	INDICATION	AVERAGE POPULATION AGE	PROPORTIONAL SHORTFALL	ABSOLUTE SHORTFALL	WEIGHTING APPLIED IN DECISION-MAKING?	EVALUATION OUTCOME
TA862[3]	Trastuzumab deruxtecan	HER2-positive unresectable or metastatic breast cancer	53 years	Not met for EAG or company	Met for 1.2 weighting in company scenario	No	Recommended for use in CDF
TA866[4]	Regorafenib	Previously treated metastatic colorectal cancer	60 years	Met for 1.7 weighting (for one subgroup)	Not discussed in final evaluation document	Yes 1.7 to one subgroup	Recommended for routine commissioning
TA896[5]	Bulevirtide	Chronic hepatitis D	35 years	Not discussed in final evaluation document	Met for 1.2 in all but 1 of the company's scenario analyses	Yes 1.2	Recommended for routine commissioning

CONCLUSION

- The severity modifier has been proposed in few evaluations so far, less than the proportion that NICE's analysis suggested would have applied for evaluations from 2011 to 2019 (~39%)[6.]
- The NICE committee has generally needed convincing evidence to apply the modifier, although recognised the need to accept greater uncertainty in rare diseases in TA896
- Despite not officially recommending the Schneider tool, NICE has referred to it as a potential "helpful resource" and manufacturers have notably been using this within appraisals[7]
- During development of the severity modifier, some consultees suggested that older populations may have difficulty in qualifying for it6. NICE considered this unlikely to be an issue and it is interesting to note that in TA866, where proportional shortfall was met, the average population age was 60 years old
- Future research after further implementation of the severity modifier will enable greater insights

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