

How end of life translates to severity weighting under the new National Institute for Health and Care Excellence (NICE) methodology: A review of past oncology appraisals

Rachael Batteson¹, Simone Critchlow¹, Thomas Douglas¹, Keyur Patel², Safa McLachlan², Farhan Mughal²

¹Delta Hat Limited, Nottingham, UK; ²Daiichi Sankyo UK Ltd., Uxbridge, UK

Background

In February 2022, NICE updated its methods for Health Technology Assessment (HTA).¹ Within the new methods guide a quality-adjusted life-year (QALY) weighting labelled as the severity modifier was introduced to place greater value on treatments for severe diseases, effectively changing the willingness-to-pay (WTP) threshold. ‘Severity’ is quantified by the absolute and proportional QALY shortfall on current standard-of-care (SoC) relative to the general population of the same age and same sex distribution. Depending on the absolute and proportional shortfalls, one of two modifiers could be applied to the incremental QALY gain; 1.2x or 1.7x. These can be translated as £36,000 or £51,000 WTP thresholds, respectively, compared with the standard WTP threshold range of £20,000 - £30,000.

This methodology replaced the end-of-life (EOL) criteria which focused on the length of life with SoC and the extension of life a new intervention was estimated to offer (less than 24 months and greater than 3 months, respectively, to meet the EOL criteria).² Treatments that met the EOL criteria were assessed at a £50,000/QALY threshold.

The true impact of this change for EOL disease areas, particularly oncology, is unknown.

Objective

This research evaluates previous NICE oncology appraisals to estimate the absolute and proportional QALY shortfalls. From this, the QALY weightings are calculated to determine the corresponding WTP threshold that each appraisal would have been assessed at under the new framework.

Methods

A targeted literature review was conducted to identify previous NICE technology appraisals in oncology which published guidance between 1st January 2020 and 1st April 2023. All appraisals had an invitation to participate issued before the updated NICE Methods were introduced in February 2022.

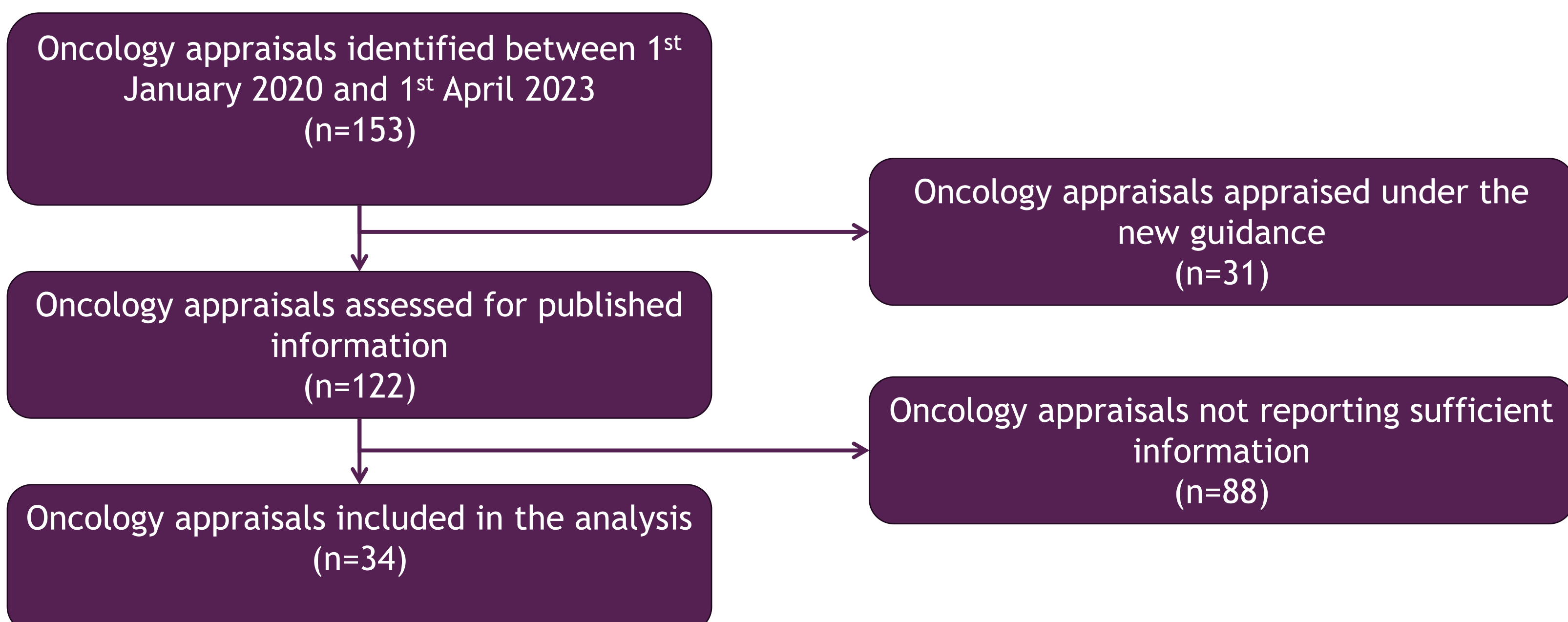
For inclusion in the analysis, the appraisal had to report the published total QALYs for the SoC (comparator) arm, as well as the patient population age and male/female distribution. These were necessary to calculate the absolute and proportional QALY shortfall. The studies identified were split into two groups; those that met the EOL criteria and those that did not.

For each appraisal included in the analysis, the severity modifier (and corresponding WTP threshold) was estimated using the QALY shortfall calculator by Schneider et al, 2021.³ The outcomes were then compared to the corresponding WTP threshold under the EOL framework (e.g., £20,000 - £30,000 or £50,000).

Results

The targeted review identified 153 oncology appraisals across the date range, of which, 122 were appraised under the previous NICE methods (i.e., meeting the £50,000 WTP if EOL was met, or £20,000 - £30,000 WTP if EOL wasn’t met). Of the 122, 34 had sufficient information to calculate the absolute and proportional shortfall (Figure 1).

Figure 1: Identification of appraisals included in the analysis

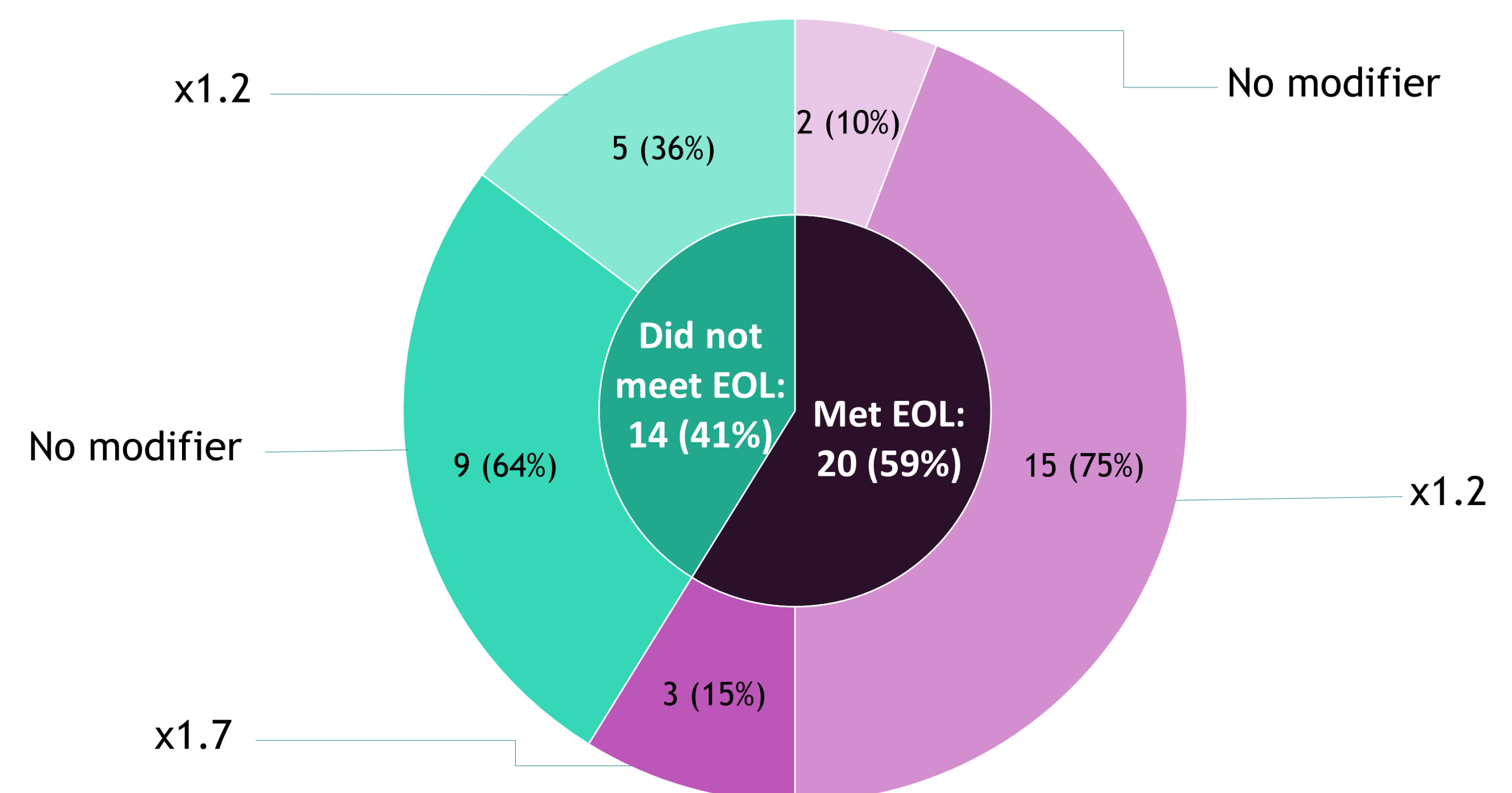


The 34 appraisals were assessed based on whether they met the EOL criteria. The QALY weighting was estimated using the Schneider tool to calculate which modifier the appraisal would have met if appraised under the new methods (Figure 2 and Figure 3).

Of the 34 appraisals, 20 (59%) met the previous EOL criteria. Of these 20, 17 (85%) would now have been appraised under a lower WTP. Three of the 20 (15%) would meet the 1.7x QALY weighting and 15 (75%) would meet the 1.2x QALY weighting under the new methods. Two appraisals that previously met the EOL criteria (10%) would receive no weighting under the new methods.

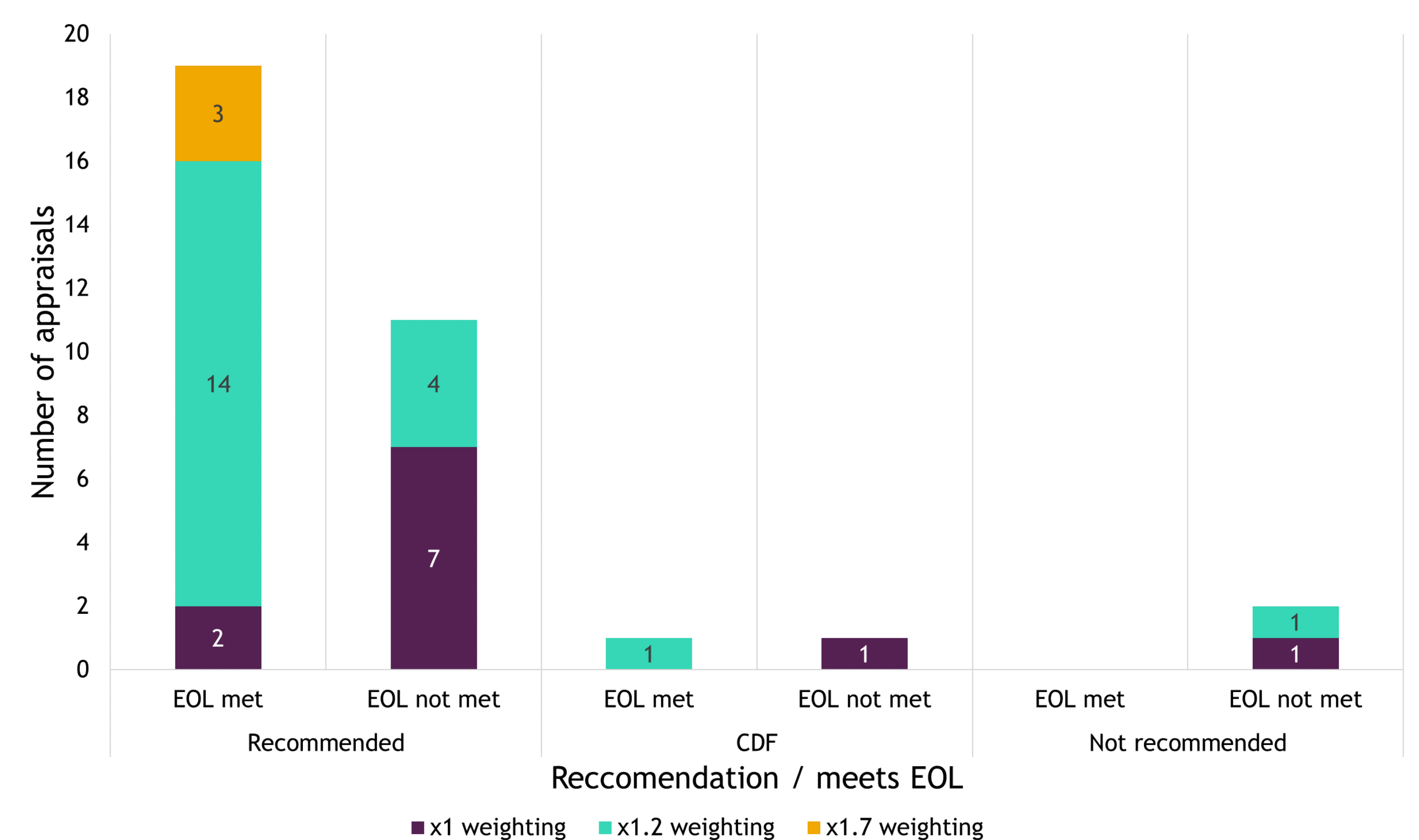
Fourteen (41%) of the 34 appraisals did not meet the previous EOL criteria. Of the fourteen, five (36%) would now be appraised at a higher threshold with the 1.2x QALY weighting. None of the indications would be considered under a 1.7x QALY weighting.

Figure 2: Severity modifier by EOL criteria



Key: EOL, end of life

Figure 3: Severity modifier by EOL criteria and NICE recommendation



Key: CDF, Cancer Drugs Fund; EOL, end of life

The weighted average threshold was calculated using the number of appraisals and WTP thresholds. The previous methods under the EOL criteria results in an average threshold of £41,765 for oncology appraisals considering the 20 meeting EOL at the £50,000 WTP and 14 not meeting EOL at the £30,000 WTP [(20 x £50,000 + 14 x £30,000)/34]. In comparison the severity modifier weighted average threshold would be £35,382 considering 3 appraisals meeting the £51,000 WTP, 20 meeting the £36,000 WTP and 11 remaining at the £30,000 WTP [(3 x £51,000 + 20 x £36,000 + 11 x £30,000)/34].

Conclusions

This analysis is limited by the small sample of prior oncology appraisals with publicly available information needed to estimate the absolute and proportional QALY shortfall. However, of the 34 appraisals identified and analysed, results suggest that whilst the majority of previous EOL treatments would meet the criteria for at least the 1.2x severity modifier weighting under the new framework, most would not meet the criteria for the 1.7x QALY weight (i.e., broadly commensurate to the previous EOL criteria).

Findings from this analysis, and the estimation of the corresponding severity modifiers, indicate that the average WTP threshold accepted for oncology appraisals by NICE under the new framework for QALY weighting would be reduced in comparison to the previous EOL approach. This suggests that, despite the potential benefits of this new approach (i.e., broader assessment of severity across conditions), the macro-scale outcome of this approach may impact patient access to innovative oncology treatments in England and Wales.

References

- NICE (2022). Available at: <https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation>
- NICE (2013). Available at: <https://www.nice.org.uk/process/pmg9/chapter/foreword>
- Schneider et al (2021). Available at: <https://shiny.york.ac.uk/shortfall/>