NICE'S Severity Modifier: Insights From Recent Appraisals

Treharne C , Gill A
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Health Analytics, Lane Clark & Peacock LLP.
London, UK

Summary

- In the 12-month period ending May 2024, a severity modifier was applied in 30% of eligible NICE single technology appraisals (n = 14/46). The higher severity modifier (x1.7), which aligns most closely with the former end-of-life criteria, was applied in 11% of appraisals (n = 5/46).
- The severity modifier was predominantly applied in appraisals for cancer treatments, and in appraisals for blood cancer treatments in particular (n = 6/14).
- The average population age was lower in appraisals where a severity modifier was applied (43.0 vs 56.5; p = 0.195).
- Inconsistent reporting of QALY shortfall calculations currently limits transparency and comparability across appraisals.

Background

- In February 2022, NICE introduced the severity modifier to provide additional weighting for medicines treating more severe conditions.[1]
- This replaced the previous 'end-of-life' criteria, which gave greater weight to treatments extending survival in the terminal stages of a rare disease. The severity modifier now considers both quality of life and life expectancy to assess overall disease severity.
- Data from the first year of implementation of the 2022 methods manual showed that fewer topics qualified for the severity modifier than had been expected.[2] In August 2024, the Association of the British Pharmaceutical Industry (ABPI) publicly urged NICE to review the severity modifier and lower the thresholds for additional weight, to benefit a wider range of treatments.[3]
- We reviewed the application of the severity modifier over the 12-month period ending May 2024.

Methods

- We identified single technology appraisals (STAs) published between 01/06/2023 and 31/05/2024 and reviewed associated committee papers and guidance documents.
- We extracted information on the patient population, the company, external assessment group (EAG) and NICE committee positions on the severity modifier's applicability, as well as the appraisal outcome.
- For appraisals reporting data on baseline population age, we analysed the baseline age applied in the cost-effectiveness analysis according to whether a severity modifier was applied in committee decision making.

Results

- There were 64 appraisals that met our search criteria; severity modifiers were discussed in 46 (72%). In appraisals where the severity modifier was not discussed, the company presented a cost-comparison analysis, or the submission preceded or followed shortly after the severity modifier's introduction. All cost-utility company submissions submitted after June 2022 included discussion of the severity modifier.
- Of the cost-utility appraisals where the severity modifier was discussed, the company made a case for its application in 33% of submissions (n = 15/46).
- The severity modifier was ultimately applied by the committee in all but one of these appraisals (TA949 – Belumosudil for chronic graft-versus-host disease). In a further appraisal (TA914 – Pembrolizumab for previously treated MSI-H/dMMR cancers), the committee applied the 1.2 severity modifier rather than the originally proposed 1.7 severity modifier to gastric and small intestine tumour site quality-adjusted life years (QALYs).
- The 1.2 severity modifier was applied in 11 appraisals, with the 1.7 severity modifier applied in 5 appraisals.
- All but one of appraisals where the severity modifier was applied were in oncology, with 43% in blood cancer (n = 6/14).
- Of the 14 appraisals in which the severity modifier was applied by the committee, 93% (n = 13/14) received a positive recommendation (either full or optimised). In contrast, among the 32 appraisals where the severity modifier was not applied, the positive recommendation rate (full, optimised, or managed access) was slightly lower, at 84% (n = 27/32).
- Reporting of QALY shortfall calculations was inconsistent; companies reported calculations in all appraisals where a case for the severity modifier was made, and in only 42% of appraisals where no case was made (n = 13/31).
- As expected, the average baseline population age was lower in appraisals where a severity modifier was applied (43.0 vs 56.5; p=0.195).

64 Appraisals which met the criteria for the search

46 Appraisals where the severity modifier was discussed

15 Appraisals where the company made a case for the severity modifier

14 Appraisals where the severity modifier was applied by the committee

11 Appraisals where the 1.2x severity modifier was applied

5 Appraisals where the 1.7x severity modifier was applied

Summary of NICE Single Technology Appraisals where a severity modifier was proposed by the company (01/06/2023 – 31/05/2024)

TA	Therapy area	Treatment	Company estimate	EAG estimate	Committee estimate	Appraisal outcome
TA977	Glioma	Dabrafenib with trametinib	LGG cohort: 1.2 HGG cohort: 1.7	1.2 1.7	1.2 1.7	Recommended
TA975	B-cell acute lymphoblastic leukaemia	Tisagenlecleucel	1.7	1.7	1.7	Recommended
TA970	Multiple myeloma	Selinexor with low-dose dexamethasone	1.7	Not defined	1.7	Recommended
TA967	Hodgkin lymphoma	Pembrolizumab	1.2	1.2	1.2	Optimised
TA954	Diffuse large B-cell lymphoma	Epcoritamab	1.2	1.2	1.2	Optimised
TA952	Breast cancer	Talazoparib	1.2	1.2	1.2	Recommended
TA949	Graft-versus-host disease	Belumosudil	1.2	1	1	Recommended
TA948	Cholangiocarcinoma	Ivosidenib	1.7	1.7	1.7	Recommended
TA947	B-cell lymphoma	Loncastuximab tesirine	Chemotherapy comparison: 1.2 Pola-BR comparison: 1	1.2 1	1.2 1	Optimised
TA944	Biliary tract cancer	Durvalumab with gemcitabine and cisplatin	1.2	1.2	1.2	Recommended
TA928	Thyroid cancer	Cabozantinib	1.2	1.2	1.2	Not recommended
TA927	B-cell lymphoma	Glofitamab	BR comparison: 1.2 Pola-BR comparison: 1	1.2 1	1.2 1	Recommended
TA914	MSI-H/dMMR cancers	Pembrolizumab	Gastric: 1.7 Small intestine: 1.7 Biliary: 1.7 Colorectal: 1.2 Endometrial: 1.2	1.2 1.2 1.7 1.2 1.2	1.2 1.2 1.7 1.2 1.2	Optimised
TA911	Non-small cell lung cancer	Selpercatinib	1.2	1.2	1.2	Optimised
TA896	Hepatitis D	Bulevirtide	1.2	1.2	1.2	Optimised

Note: Green cells denote appraisals where the EAG/Committee agreed with the company's assessment of severity modifier eligibility; red cells denote instances where there was disagreement.
Abbreviations: BR, rituximab with bendamustine; EAG, external assessment group; FLAG-IDA, fludarabine cytarabine iDArubicin and filgrastim; HGG, high-grade glioma; LGG, low-grade glioma; pola-BR, polatuzumab vedotin with rituximab and bendamustine; TA, technology appraisal.

Conclusions

- In the 12-month period ending May 2024, a severity modifier was applied in 30% of eligible STAs (n = 14/46). The higher severity modifier, which aligns most closely with the former end-of-life criteria, was applied in 11% of eligible appraisals (n = 5/46). Based on the period of our analysis, severity modifiers were predominantly applied in cancer indications (93%, n = 13/14).
- In September 2024, the Board of NICE concluded that the severity modifier 'is working as intended' but agreed to continue monitoring the impact of its introduction. Further, the Board intends to commission additional research to understand society's preferences in terms of valuing medicines for severe diseases.[4]
- The timing of this update coincided with a report from the NICE Decision Support Unit (DSU), which concluded that it may be too early to draw conclusions about differences in the distribution of severity weights between post-2022 appraisals and those observed pre-2022, which informed the calculation of severity weights and the cut-off thresholds for absolute and proportional QALY shortfall.[2]
- In the meantime, more consistent reporting of severity modifier calculations in line with the NICE DSU's Technical Support Document (TSD23) would enhance transparency and comparability across appraisals.[5]

References:
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