



Policy for appraising medicines for severe conditions

This policy should be read in conjunction with the following documents:

- **AWMSG appraisal principles & process flowcharts**
- **AWMSG Form B guidance notes**
- **AWMSG Guidance on appraisal structure and evidence**
- **NICE health technology evaluations: the manual. Process and methods (PMG36).**

Background

In July 2022, the All Wales Medicines Strategy Group (AWMSG) endorsed the adoption of a severity modifier. The modifier supports resource allocation decisions which better reflect social values and preferences. It also aligns AWMSG and the National Institute for Health and Care Excellence (NICE) health technology assessment (HTA) methodologies, and facilitates more equitable access to medicines in Wales.

Assessing the severity of a condition

When appraising a medicine, AWMSG will consider the severity of the condition being treated. Severity is defined as the future health losses of people living with the condition who are receiving standard NHS care (that is other current treatments or best supportive care)¹.

To assess the severity of a condition, AWMSG will consider both absolute and proportional quality-adjusted life-year (QALY) shortfalls:

- **Absolute QALY shortfall** captures the absolute future health that is lost by people living with the condition, in terms of quality and quantity of life. This shortfall is calculated by taking the total QALYs that people with the condition would be expected to have over their remaining lifetime whilst receiving current established NHS treatment, and subtracting it from the total QALYs that the general population would be expected to have over their remaining lifetime (adjusting for the age and sex distribution of the population)¹.
- **Proportional QALY shortfall** captures the proportion of future health that is lost by people living with the condition, including quality and quantity of life. This shortfall is calculated by dividing the absolute QALY shortfall by the remaining expected future health of the general population (adjusting for the age and sex distribution of the population)¹.

The QALY shortfall estimates should be informed by recent and robust data sources for survival and health-related quality of life (EQ-5D). An annual discount rate of 3.5% should be used to calculate QALY shortfall estimates.

Applying a severity modifier

The absolute or proportional QALY shortfall value will determine what weighting is applied to the QALYs for a medicine (Table 1). AWMSG may assign a greater weighting to QALYs if the assessments of QALY shortfall show that the medicine is to treat a condition that has a high degree of severity.

If the absolute and proportional QALY shortfalls imply different levels of severity, QALY weighting selection is guided by the shortfall that shows greatest severity¹. See the Form B Guidance notes for further information on these two measures of severity.

Table 1. Severity modifier – QALY weightings¹

Absolute QALY shortfall	Proportional QALY shortfall	QALY weight
Less than 12	Less than 0.85	1
12 to 18	0.85 to 0.95	1.2
Greater than or equal to 18	Greater than or equal to 0.95	1.7

Medicines that have received a positive recommendation from AWMSG after applying the severity modifier will not necessarily be regarded, or accepted, as standard comparators for future appraisals of new medicines developed to treat the same condition. To be regarded, or accepted, as a comparator, a medicine must be available for routine use and represent established and current NHS practice at the time of an appraisal.

Medicines previously appraised by NICE, or submitted to AWMSG for a second or subsequent appraisal (for different indications), will be considered on their individual merits.

Note: no additional severity modifier QALY weighting is applied to medicines developed to treat very rare diseases; severity is implicit in the application of the medicines for very rare disease policy for those medicines.

Process for appraising a medicine to treat a severe condition

The appraisal process for a medicine for a severe condition aligns with AWMSG’s process for appraising other medicines (see AWMSG Guidance on appraisal structure and evidence).

When making a submission to AWMSG, the applicant company should make it clear in the Form B that it considers the severity modifier to be applicable. The All Wales Therapeutics and Toxicology Centre (AWTTC) will take this into account when assessing the information and preparing the AWMSG Secretariat Assessment Report (ASAR). In the ASAR, AWTTC will state its view about whether the severity modifier

should apply. If the severity modifier is considered not to apply, the applicant company will have the opportunity to challenge this decision in its response to the ASAR.

The New Medicines Group (NMG) will take account of the applicant company's response when making a preliminary appraisal recommendation (PAR) to AWMSG. Following the NMG meeting, the applicant company will have opportunity to comment on NMG's PAR. The key factors influencing NMG's decision will form part of the PAR.

AWMSG will consider the applicant company's written response to the PAR. The applicant company will also have the opportunity to respond verbally at the AWMSG meeting. In appraising the medicine, AWMSG will have the final decision about whether to apply the severity modifier.

References

1. National Institute for Health and Care Excellence. Process and Methods Guidance 36. NICE health technology evaluations: the manual. Jan 2022. Available at: <https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation>. Accessed Nov 2022.