

**AWMSG POLICY ON APPRAISING  
LIFE-EXTENDING, END-OF-LIFE MEDICINES**

---

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

- **AWMSG appraisal principles & process flowcharts**
- **NICE supplementary advice to the Appraisal Committees on appraising life-extending, end-of-life treatments**

Additional criteria will be taken into account by the New Medicines Group (NMG) and the All Wales Medicines Strategy Group (AWMSG) when appraising medicines which may be life-extending for patients with short life expectancy, and which are licensed for indications affecting small numbers of patients with incurable illnesses.

The criteria for appraising life-extending, end-of-life medicines apply when the most plausible incremental cost-effectiveness ratio (ICER) estimate exceeds £30,000 per quality-adjusted life-year (QALY) gained, and the following conditions are satisfied:

- The medicine is indicated for patients with a short life expectancy, normally less than 24 months (e.g. estimated from the median survival of patients in the control group of the pivotal study) and;
- There is sufficient evidence to indicate that the medicine offers an extension to life, normally of at least an additional three months, compared to current NHS treatment. The estimates of the extension to life should be robust and shown (or reasonably inferred) from either progression free survival or overall survival.

When these conditions are met, NMG/AWMSG will consider:

- The impact of giving greater weight to QALYs achieved in the later stages of terminal diseases, using the assumption that the extended survival period is experienced at the full quality of life anticipated for a healthy individual of the same age, and;
- The magnitude of the additional weight that would need to be assigned to the QALY benefits in this patient group for the cost-effectiveness of the medicine to fall within the current threshold range.

In addition, NMG/AWMSG will need to be satisfied that:

- The estimates of the extension to life are robust and can be shown or reasonably inferred from either progression free survival or overall survival (taking account of trials in which cross-over has occurred and been accounted for in the effectiveness review) and;
- The assumptions used in the economic modelling are plausible, objective and robust.

Medicines receiving a positive recommendation from AWMSG following the application of these criteria will not necessarily be regarded, or accepted, as standard comparators for future appraisals of new medicines introduced for the same condition.

Medicines previously appraised by the National Institute for Health and Care Excellence (NICE), or submitted for a second or subsequent appraisal by AWMSG (for different indications), will be considered on their individual merits.

An advice review date may be set to ensure that additional clinical trial evidence or clinical audit data is reviewed, and this may require an additional submission.

### **Process for consideration of the application of NICE's End of Life Criteria (EoLC)**

Within their submission (i.e. in Form B) the applicant company should provide an explanation as to why they consider EoLC is applicable. In their assessment of the company submission (i.e. within the ASAR), AWTTTC will consider the company's rationale and will comment on the applicability of the EoLC. The ASAR will be provided to the applicant company for comment ahead of the NMG meeting. If the company do not agree with AWTTTC's views regarding the applicability of the EoLC, then they should highlight their reasons within the CR/ASAR. NMG will take account of the applicant company's response in line with the ASAR when making a preliminary recommendation to AWMSG.

Following the NMG meeting, the applicant company will have opportunity to comment on NMG's preliminary appraisal recommendation (PAR). The key factors influencing NMG's decision will form part of the PAR.

An appraisal can be suspended at any time during the appraisal process if it is considered that there are outstanding issues that need to be addressed. A request for suspension can be submitted by the applicant company, AWTTTC or NMG/AWMSG. This request will be considered by the AWMSG Steering Committee and the process may or may not be suspended. If it is agreed that the process should be suspended so that issues relating to the end of life criteria can be explored more fully, a panel will be convened.

The role of the End of Life Panel will be to consider whether the evidence provided by the applicant company is sufficient to satisfy members that the conditions for end of life (as outlined above) have been met.

Panel members will be identified by AWTTTC and a meeting arranged (usually within six weeks of the request with the applicant company). The AWMSG Chairman will be excluded from the discussion. The panel will comprise of seven members:

- Three members or deputy members from NMG or AWMSG past or present (appointment to this panel would exclude a member from voting at the subsequent appraisal by AWMSG).
- Four members from Medicines and Therapeutics Committees (MTCs), AWTTTC and/or other experts in the relevant scientific field who may or may not work in Wales.

One of the above individuals will be appointed to chair the panel.

The applicant company delegates will be invited to participate in the discussion but will not be eligible to vote.

A clinical expert may be invited to attend to input into discussions but will not be eligible to vote.

The outcome of the end of life panel meeting will be relayed to AWMSG.

In appraising the medicine AWMSG will have the final decision as to whether or not the EoLC should be applied.

Flowchart outlining AWMSG's process for consideration of the applicability of NICE's End of Life Criteria (EoLC)

