

The Charity Medicines Access Coalition (CMAC) George Lankester who Chairs the Alliance summarises CMAC's reactions to the outcomes:

Methods

- Severity modifier - Of the two options that were proposed, our preferred option will be adopted. However, we were disappointed with the ambition of both options. It is felt that those medicines which do qualify will likely fall into a lower cost-per-QALY threshold than would be seen under the current End-of-life modifier. We supported the idea of an additional threshold which may allow more new, innovative medicines to benefit from the modifier. More widely, this was viewed to fall under cost-neutral ambitions that were not touched on by NICE as necessary at earlier stages of the consultation. NICE do not appear open to a new approach, but there is a workshop due to be held to go over new proposals in more detail.
 - Implementation was discussed at the board meeting and it is regarded as “quite a change” that will take several months to implement. As known previously, there will be further research to ‘refine the modifier further’ and to look at how great society values the modifier’s role.
- There is still no clear direction and approach to how NICE will implement a health inequalities modifier. We think it is important a clear timeframe and process is put in place for developing this proposal further.
- CMAC asked for further guidance on what could be considered acceptable or unacceptable uncertainties, and the approach to inherent uncertainties. NICE have provided further clarity on this, with additional text on when and how additional consideration of uncertainty where evidence generation is difficult should be applied.
- There has been no progress with regards to a reduction in the rate of discounting. Our position is that – “a fair assessment of the rate of future discounting is pivotal for diseases with long-term progression, and if affordability concerns restrict this change, the system cannot be said to be meeting the ambition of the Government Life Sciences Vision to open up patient access to new, innovative treatment”.
- There is no acknowledgement of concerns identified relating to health related carer quality of life, though it is referenced as a possible subject for future modular reviews.
- CMAC are concerned by the proposal to not recommend a technology for a particular subgroup for which the technology is not cost-effective even when the technology is found to be clinically and cost-effective for the whole population. This could lead to an increased number of “optimised” recommendations, unnecessarily restricting access and facilitating health inequalities amongst patient populations. We believe NICE appraisals should start from the principle of considering the whole population a treatment is licenced for, not restricting access to certain subgroups. NICE have not changed their position on this.
- Conversations are ongoing around governance arrangements for future modular reviews and what stakeholder engagement will look like with regards to prioritising topics.

Process

- CMAC's key process review asks in the most recent consultation stages were centred around improved training for committee members, greater clarity on who is responsible for technical engagement where it will deviate from standard, and further information on how NICE will be working with NHSE and the ILAP process. Greater clarity has not been forthcoming.
- NICE have reassured through the manual, however, that they will engage ‘appropriately’ with relevant stakeholders in response to concerns about stakeholder involvement within the process for managing high company base ICERs.

HST

- There has been strong concern over the new criteria for entry to HST, which were seen as a restrictive, arbitrary and overly complex.
- NICE have adapted the criteria requirements to say that for a technology to be considered through the programme it will only need to fulfil 4 criteria rather than 7 previously. This is positive, but not the one clear single point of entry that patient organisations would like to see.