National Institute for Health and Care Excellence

Review Guide to the Methods of Technology Appraisals Addendum - 2014

Comments

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	Consultation questions
1 Does proportional QALY shortfall appropriately reflect burden of illness?	Yes. Motor neurone disease (MND) shortens life and impairs its quality drastically. MND will therefore always register a substantial proportional QALY shortfall, and this is probably a more effective measure than the existing end of life criteria, as these cover only the last 24 months of life; although the median time from diagnosis to death in cases of MND is only 14 months, a significant minority of people live longer than 24 months, so proportional QALY shortfall will capture these people as well as the average-to-fast progressing cases.
2 Does absolute QALY shortfall provide a reasonable proxy for wider societal impact of a condition?	No. We welcome the shift from the formerly proposed approach of assessing 'wider societal benefit' to 'wider societal impact'; MND disproportionately affects older people, and even when people of working age are diagnosed it will force them to leave the labour market, so looking at the issue in relatively narrow economic terms, as the original approach proposed, risked disadvantaging new treatments for MND. Absolute QALY shortfall still has these biases to some extent, however, as it is influenced by factors such as age and gender. We feel that absolute QALY shortfall has significant limitations as a proxy for wider societal impact. We would prefer to see a new methodology developed that allowed for the consideration of qualitative evidence from patients and clinicians about the benefits of the intervention at issue.
3 Does a maximum weight of 2.5 in circumstances when all modifiers apply function as a reasonable maximum?	No. This imposition of an absolute cap on value is too strict. As medicine develops over the coming years and decades, it will become stratified, as new treatments target specific disease subtypes (such as inherited forms of MND). This is likely to result in some new MND treatments being suitable for only a small sub-set of an already small patient population, and the cost of such a medicine is likely to be high. From the next PPRS onwards, the NHS and NICE will have to set a direction for making equitable decisions about how such high-cost medicines are made available: this could be through the regular approaches for branded medicines, or through highly specialised routes; whichever mechanism is used will likely require enhanced resources and enhanced infrastructure for decision-making. The

	implications of this shift for other care needs must also be understood: new life-prolonging treatments for diseases such as MND, which lack substantially effective therapies at present, will increase the numbers of people living with significant health problems and requiring care. Stratified medicines of this sort are only just starting to become available (none is yet available for MND), so there are a few years before this nettle must be grasped fully, but not many. Introducing an absolute cost-per-QALY cap into NICE's decision-making, without allowing for any flexibility, would not be a sound step in this context.
4 Should we allocate specific 'weights' to each of the 'modifiers' so that they add up to a maximum of 2.5? If so, do you have a view on what weight should be added in each case	No. Such an approach would be far too inflexible. We support the use of modifiers of this sort to rule treatments in, because they might have one particularly valuable aspect. We would be concerned at any insistence that all new treatments satisfy all the modifiers, particularly within a highly specific system of weighting, as the net effect of this will undoubtedly be to rule new treatments out.
5 Will the approach outlined in this document achieve the proposed objectives of improving consistency, predictability and transparency in the judgements made by our independent Appraisal Committees when they consider the clinical and cost effectiveness of health technologies?	We feel this approach will probably make little overall difference unless it is implemented with the strict conditions about which we express concern above, in which case it will have a negative impact. If implemented this way, it is likely to lead to more consistency only in as much as more drugs will be excluded from funding.
6 Are there any risks which might arise as a result of adopting the value-based assessment approach as outlined above? If so, how might we try to reduce them?	
7 Are there any other comments you wish to make?	Please enter these comments in the table below

Paragraph Number Primarily Related to your Comment (please enter only one) Indicate **'general'** if your comment relates to the whole document	**Other Paragraph Numbers Related to your Comment**	**Comments** **Please insert each new comment in a new row.** **Please do not paste other tables into this table, as your comments could get lost – type directly into this table.**

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Closing date: Friday 20 June 2014 5pm

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