

**Response to the Appraisal Consultation Document:
Lenalidomide for the treatment of multiple myeloma in people who have received at
least one prior therapy from Macmillan Cancer Support**

November 2008

We are extremely disappointed that the recently issued ACD on the use of lenalidomide for the treatment of multiple myeloma in people who have received at least one prior therapy is negative and we do not feel that the preliminary recommendations reflect the needs of this small patient group.

1. Do you consider that all of the relevant evidence has been taken into account?

1.1 This is a very difficult patient group to treat – with limited options for many that relapse – time to progression and response rates including overall survival are better with lenalidomide plus dexamethasone compared to dexamethasone alone. This treatment therefore presents patients with a much better option than is currently routinely available within the NHS.

1.2 As outlined in point 4.2 of the ACD it is acknowledged that patients, carers and physicians all believe that lenalidomide is an important advance in treatment for multiple myeloma and that it is vital that there are treatment options available within the NHS for treating patients after relapse. We are concerned that this does not seem to have any weight in the evaluation of the evidence and would ask the Committee to reconsider the needs of this small patient population.

2. Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence, and that the preliminary views on the resource impact and implications for the NHS are appropriate?

2.1 We are concerned that the EQ5D measure of quality of life does not have a dimension which adequately captures energy or fatigue. One of the main symptoms of myeloma is excessive tiredness and lethargy due to a lack of red blood cells (anaemia). Therefore energy and fatigue are very important considerations in treatment of myeloma patients, particularly as their disease progresses and must be considered by the Appraisal Committee. This is not captured in the utility scoring and as this is a known shortcoming in the analysis we would like to see how this issue is being considered by the Appraisal Committee.

2.2 We are also concerned that when clinical trials allow patients to cross over to the other arm of the trial at unblinding, this degrades the clinical trial data, as described in point 3.4 of the ACD. This makes the data less compelling because end points are

not reached in the control arm. We would ask the Appraisal Committee to consider this important clinical trial data again.

3. Do you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS?

3.1 We do not believe that the provisional recommendation constitutes suitable guidance to be implemented by the NHS.

3.2 As outlined above (point 1.1) we are concerned that the evidence supplied by patients, carers and clinicians does not seem to have been given significant weight in the consideration of the evidence.

4. Are there any equality related issues that need special consideration that are not covered in the ACD?

4.1 The NICE Citizen's Council recommends that NICE and its advisory bodies should take the severity of a disease into account when making decisions. The NICE Board has subsequently accepted these recommendations and we would urge the Appraisal Committee to take these recommendations into account now so that the most patients will be able to benefit. We would like to see, in the 'Evidence and interpretation' section, whether the Appraisal Committee was persuaded in this instance to take the severity of this condition into consideration alongside the cost and clinical effectiveness evidence.

5. Other comments

5.1 We would urge manufacturers to put forward a risk-sharing agreement to reduce the QALY to make these treatments more likely to be considered cost effective.

5.2 According to the UK Statistics Authority the 'Cancer statistics registration – Registrations of cancer diagnosed in 2005, England' stated that there were 3,243 newly diagnosed cases of multiple myeloma in 2005. This therefore falls well below the proposals which NICE is currently consulting on in relation to the appraisal system for medicines at the end of life. We would hope that the Committee is minded of this consultation and considers the proposal outlined in it when making its final recommendations.

5.3 As a charity dealing with patients and their families being denied treatment for myeloma, we are more than disappointed that the committee is minded to reject this treatment which is important to patients. We believe that this treatment should be made available to those that would benefit from it, on the basis of clinical decision making, rather than on purely cost-effectiveness grounds.