Tuesday, 07 November 2006

We write as representatives of the UK Myeloma Forum, consultees to the appraisal of Bortezomib monotherapy for relapsed multiple myeloma, to appeal against the Final Appraisal Determination.

Our appeal is on two grounds;

Ground 1)
That the institute has failed to act fairly and in accordance with its published procedures as set out in the Institutes Guide to the Technology Appraisal process by failing to engage effectively with consultees to define the appropriate scope of the appraisal.

- It is a failure of process and unfair not to have an appraisal scope
- Had the UK Myeloma forum been involved in the scoping process, we would have had an opportunity to demonstrate that Bortezomib and Dexamethasone, both licensed for the treatment of myeloma, are combined in routine clinical practice in the UK and in the rest of the world. The UKMF would therefore have advised that the appropriate decision framework was to evaluate the efficacy and cost effectiveness of bortezomib when combined with Dexamethasone
- Had this evidence been accepted and taken into account, the cost effectiveness of Bortezomib would have been shown to be within acceptable limits (below £30,000/QALY) and thus final NICE guidance would have been to recommend its use in first relapse

Ground 2)
That the institute has prepared a FAD that is perverse in the light of the evidence submitted.

It is perverse to have failed to consider the increased efficacy of the combination of Bortezomib and dexamethasone in its cost effectiveness calculations because

a) Both Bortezomib and dexamethasone are licensed for the treatment of myeloma.
b) There is a wealth of evidence showing that the efficiency of Bortezomib is significantly improved by combining it with Dexamethasone [1234]
c) UK clinicians routinely use the combination of both drugs in clinical practice[4]

Furthermore, in not allowing the combination of two licensed agents to be considered together in the scope of the appraisal, there is a perverse disincentive to undertake randomised controlled trials and seek a licence for drugs and a disincentive to the pharmaceutical industry to invest in research to develop agents for the less common cancers.

We very much welcome the fact that NICE have acknowledged that Bortezomib is clinically effective. However the decision not to recommend Bortezomib on the grounds of cost effectiveness will deprive myeloma patients of the first real proven advance in the treatment of myeloma for many years. Because of this some patients will die before having access to other new drugs which are currently in development and showing promise in myeloma so that this decision effectively shortenss survival significantly and more obviously than at first examination.

Thus the UKMF request that the appeals committee consider these points and advise the appraisal committee to re-evaluate its cost effectiveness decision of Bortezomib on the basis of its efficacy when combined with dexamethasone at first relapse.

1 Suvannasankha et al. Blood 2005;106 (Abstract 2562)
2 Jagannath S, et al. ASH 2005, abstract #783
3 Richardson et al N eng J Med 2003 348 2609 -17
4 Morris C personal communication of Northern Irish data

Chairman
Treasurer
Secretary

Signed electronically by members of the executive committee of the UKMF on behalf of the members of the UKMF