The Royal College of Pathologists

Joint submission from the Royal College of Pathologists and the British Society for Haematology

NICE Final Appraisal Determination - Bortezomib monotherapy for relapsed multiple myeloma

It is fair to say there is extreme disquiet about the FAD in the haematology community and we write representing the community to urgently request that an appeal is considered very seriously.

Our appeal is on 2 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 sufficiency with consultees to initially define the appropriate scope of the appraisal.

- It is a failure of process and unfair not to have an appraisal scope.
- Had the consultees 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. The BSH and RCPath would therefore have advised ,that the appropriate decision framework was to evaluate the efficacy and cost effectiveness of Velcade 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) 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.

d) That the institute failed to take into account that the safety committee of the APEX trial stopped the trial early and allowed patients in the control arm to cross-over to the velcade arm. This means that any advantage to velcade over high dose dexamethasone would have been diluted thus artificially inflating the cost per QALY for the agent

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 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 being developed and showing promise in myeloma so this decision effectively shortness survival significantly more than is obvious at first examination.
Thus the entire haematology community via the BSH, the RCPath and the UKMF request that the appeals committee consider these points and advise the appraisal committee to re-evaluate its cost effectiveness decision of Bortezomib combined with dexamethasone at first relapse.

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

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