From: [redacted] [redacted]
Sent: 27 November 2008 12:14
To: Jeremy Powell
Cc: [redacted]; [redacted]
Subject: lenalidomide for multiple myeloma

27th November 2008

Single technology appraisal (STA)
Lenalidomide for multiple myeloma in people who have received at least one prior therapy

Appraisal consultation document

I am responding on behalf of Sandwell PCT (formal consul tee) for the appraisal consultation for lenalidomide for multiple myeloma in people who have received at least one prior therapy. I would like to thank NICE for offering Sandwell PCT the opportunity to comment on this appraisal.

In response to the general questions:

i) Do you consider that all of the relevant evidence has been taken into account?

Yes, we think that you have considered all the relevant evidence that is available in the public domain.

ii) 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?

Yes, we think that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence.

iii) 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?

Yes, we consider that the provisional recommendations of the Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS.

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

No, we are not aware of any issues that need special consideration.

Specific comments

· We concur with the conclusions of the draft appraisal.

· We agree that multiple myeloma is an incurable disease and that lenalidomide is a clinically effective medicine for this condition.

· Lenalidomide has a considerable side effect profile that is however less toxic compared to thalidomide. However, the current knowledge is based on a small cohort of patients recruited for the multiple myeloma patients.

· We are also concerned that if a patient is started on lenalidomide, it is unclear for how long it will be administered. It would also be helpful if more clarity was provided on the preferred sequence of treatments, the length of treatment, and to define progression and clinical response (e.g. defined objective outcome measures and exit criteria). It will be also useful to define any sub group of patients that may benefit more than others (if appropriate).

· We think that the RCTs of lenalidomide do not have appropriate comparator such as thalidomide or bortezomib and that the high degree of crossover (47%) from control to the active arm makes very difficult the quantification of the likely degree of benefit. We are concerned that these questions are not likely to be addressed.

· Thromboprophylaxis (such as low molecular weight heparin or warfarin) is recommended in patients receiving lenalidomide, who have additional risks for thrombosis.

· Sandwell PCT has received individual funding requests for lenalidomide in multiple myeloma and after appraising the published literature/evidence, we came to similar conclusions, i.e. that lenalidomide within the cancer treatments, is relatively effective and a promising therapy, but when the balance of costs and health benefits were considered, it was thought not to be cost effective in its current pricing and not affordable, given that this is a relatively common condition. The opportunity costs are considerable for a health organization that has to fund health care across the board for its whole population. We would be happy to consider funding if the cost was reduced.

· We are not in a position to comment on technical details of the economic analysis.

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Sandwell PCT