From: [redacted], [redacted] [[redacted]]
Sent: 20 February 2009 16:17
To: David Bevan
Cc: Jeremy Powell; [redacted], [redacted]; [redacted], [redacted]
Subject: Multiple myeloma - lenalidomide: ACD - Sandwell PCT

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Sandwell PCT
Response to the NICE single technology appraisal (STA)
Lenalidomide for multiple myeloma in people who have received at least one prior therapy -
Appraisal consultation document

Dear Mr Powell,

I would like to thank NICE for offering Sandwell PCT the opportunity to comment on this
appraisal consultation whether to fund lenalidomide for multiple myeloma in people who have
received at least one prior therapy. We are making this submission on behalf of Sandwell PCT
(formal consultee) and ask you to note the following points:

In summary, we do not support the ACD provisional recommendations as we believe that the
economic case has not been demonstrated.

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?

No, we do not concur with the provisional recommendations of the Committee and we do not think that they 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 equality issues that need special consideration.

Specific comments

1 In the event that NICE approves this drug, it should provide a clear definition of who should be eligible for this drug, e.g. does NICE propose the use of lenalidomide only after receiving two treatments or as 3rd, 4th, 5th etc line of treatment. Furthermore, it would also be helpful to provide a definition of what constitutes a course of treatment (paragraph 1.1).

2 NICE should make clear whether VAT has been incorporated in its cost effectiveness assessments (paragraph 2.3).

3 It is not clear why NICE has not included decrements for adverse effects (paragraph 3.13).

4 We agree that the preferable method of calculation is using the means and not the medians. Although the former is not perfect, it is a much better approach giving more plausible results (paragraphs 3.16, 4.10, and 4.15).

5 It is not clear how the incremental life-year gain, the incremental QALY gain and the ICERs were derived (paragraphs 3.20 and 3.22). It will be helpful to make these calculations more explicit.

6 It is not clear how NICE derived the figures of 17% and 11% of patients who would benefit from a capping scheme. Is this based on NHS everyday experience or modelling (based on what evidence?) (paragraph 3.21).

7 It is important that NICE clarifies the optimal sequence of agents in treating multiple myeloma (paragraph 4.2).

8 In our view, bortezomib and thalidomide are both used enough in everyday clinical practice to justify being used as comparators and as a result dexamethasone is not the best comparator (paragraphs 4.3 and 4.4).

9 We agree that ICERs per QALY are likely to be higher (paragraphs 4.12 and 4.13).

10 We agree with NICE conclusion that use of lenalidomide for the treatment of multiple myeloma in people who had received only one prior therapy is not cost effective (paragraph 4.14).

11 It is not clear the logic behind the argument in paragraph 4.19.

Furthermore, we would like to reiterate the comments we made during the first consultation appraisal:

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

13 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 lenalidomide studies.

14 We are also concerned that if a patient is started on lenalidomide, it is unclear for how long it should 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).

15 We think that the RCTs of lenalidomide do not have appropriate comparators 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.

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

17 Sandwell PCT has received individual funding requests for lenalidomide in multiple myeloma

and after appraising the published literature/evidence, we came to the conclusion 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.

Finally, we would like to take the opportunity to reiterate our disappointment with the consultation
process so far. We are aware that our comments submitted for the first appraisal document of
lenalidomide were reported in the large (244 pages) appendix document. However, on the
Committee day, on 6th January 2009, there was no acknowledgement or discussion of our
comments. We have responded to this consultation because we think that providing a PCT
perspective is desirable and useful to NICE that has to make at times very difficult decisions. On
the day, it appeared that the only comments that were considered and debated were the ones
from Celgene and the ERG.

In our opinion, ultimately to fund or not to fund a drug is a policy decision that can only be helped
and supported by the health economic analysis and not substituted by it. So, however important
that it may be, whether we should consider the median or the mean for the control group, this
detail can not and should not be the deciding factor whether NICE agrees to fund lenalidomide.

As we have already noted in our submission to the NICE consultation on ‘Appraising end of life
medicines’, this appraisal is an example of the consequences of the application of the new rules.
The proposed treatment offers poor value for money and is not affordable within the current
funding streams. It is likely to contribute to the distortion of priorities across the spectrum of
health and health care and to incur opportunity costs to Sandwell Primary Care Trust. In the
absence of additional funding streams, this will be to the detriment of funding for other end of life
care. For Sandwell PCT, a greater priority is for example the development of an NHS hospice to
meet the needs of our population.

If this proposal is approved, it will make it much harder to decline funding for any 'rule of rescue'
end of life treatment of marginal benefit. It will also affect our ability to make reasonable
judgments in assessing the value of other new technologies not appraised by NICE and
effectively open the door to the wide use of poor value treatments.

Please confirm that you have received our e-mail.

Sincerely yours,

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