**Sara Hopkins**

**From:** Belinda Kemball [redacted]
**Sent:** 23 April 2007 14:31
**To:** Reetan Patel
**Cc:** [redacted]
**Subject:** Biogen Idecs response to the ACD
**Importance:** High
**Attachments:** Biogen Idec ACD Response FINAL.pdf; Biogen Idec ACD Response FINAL.doc

Dear Reetan

Please find attached Biogen Idecs response to the Appraisal Consultation Document for Natalizumab for the treatment of multiple sclerosis. I have attached both a PDF and a Word document which contains our response. Please note that we have marked up the Commercial in Confidence data and this appears in the document in red text and underlined.

Please can I request that you send to me a confirmation of receipt of this email.

Further to the appraisal consultation document (ACD) dated 22 March 2007, we are pleased at the opportunity to clarify the misinterpretation within the ACD. This Executive Summary directly addresses the three headings described within the email from Laura Bridgman. The main body of the document provides evidence to support the statements within the Executive Summary.

**Do you consider that all of the relevant evidence has been taken into account?**
No.
1. The ACD has failed to consider a wide body of evidence from multiple sources showing that:

a) best supportive care is not a relevant comparator in highly active relapsing remitting multiple sclerosis;

b) current disease modifying treatments are the most appropriate comparators as evidenced by:

- the inclusion of active disease modifying treatments in the final scope (section 0)
- the statement from professional/ patient groups and nominated experts in the NICE pre-meeting briefing (section 1.2.2)
- the MS treatment pathway produced by the ERG (section 1.2.3)
- current clinical opinion (section 1.2.4.1)
- current clinical practice (section 1.2.4.2)
- controlled trial evidence (section 1.2.4.3) [redacted]

2. The ACD has failed to consider the high unmet need in people with highly active relapsing multiple sclerosis (section 2)

**Do you consider that the summaries of clinical and cost-effectiveness are reasonable interpretations of the evidence, and the preliminary views of the resource impact and**

**implications to the NHS are appropriate?**

No.

1. Clinical Effectiveness

We agree with the committee's conclusion that, 'natalizumab is clinically effective in the [rapidly evolving severe relapsing-remitting multiple sclerosis] group'.

We believe that insufficient consideration was given to the sub optimal therapy subgroup. The committee failed to recognise the subset of rapidly evolving severe patients who happen to be receiving a disease modifying treatment (i.e. those experiencing 2 or more relapse in the prior year) and therefore a subset of the sub optimal treatment group. (section 3)

2. Cost Effectiveness

The Committee should recognise the appropriateness of the active comparators in the rapidly evolving severe subgroup (as outlined above). With this conclusion, natalizumab must be considered a cost-effective use of NHS resources for the treatment of the high unmet medical need in this subgroup.

3. NHS Resources & Implications

The committee made no specific statement about the resource implications of natalizumab use within either subgroup. If natalizumab was adopted for the treatment of rapidly evolving severe multiple sclerosis the net impact on NHS resources would be negligible compared with an NHS drug budget of £94 billion in 2005 (less than £1 million in year 1 rising to approximately than £5 million in year 5). (see original submission section 7)

**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.

The provisional recommendations are based on an unfounded conclusion that is not evidence-based.

Having addressed the misinterpretations within the ACD, one must conclude that...

**There is compelling evidence to support a decision to recommend that all eligible patients that fulfil the rapidly evolving severe relapsing-remitting multiple sclerosis indication, those naïve to treatment and the rapidly evolving severe subset of those receiving a current DMT, should be treated with natalizumab, funded by the NHS.**

Belinda Kemball
National Marketing and Sales Manager
BiogenIdec UK