ASSOCIATION OF BRITISH NEUROLOGISTS
ORMOND HOUSE, 27 BOSWELL STREET, LONDON WC1N 3JZ
Tel: +44 (0)20-7405 4060 Fax: +44 (0)20-7405 4070 e-mail: info@theabn.org

23 April 2007

Reetan Patel
Technology Appraisal Project Manager
National Institute for Health and Clinical Excellence
71 High Holborn
London WC1V 6NA

Dear Mr Patel

NICE Appraisal Consultation Document: Natalizumab for the treatment of adults with highly active relapsing-remitting multiple sclerosis

I am writing to you in relation to the above Appraisal Consultation Document on behalf of the Association of British Neurologists. The view expressed in this response has been seen and endorsed by members of the Association's MS guidelines panel, listed at the end of this letter (with their conflicts of interest). The panel includes David Miller, a clinical expert for this appraisal

It is our view that natalizumab is an important new treatment that should be available to the RES group of people with MS as defined in the EMEA license, i.e. people with relapsing remitting MS who have had two disabling relapses in the last 12 months and an active brain MRI scan with one or more gadolinium enhancing lesions or a significant increase in T2 lesion load. People with RES MS have a poor prognosis because of their highly active disease, and for them the provision of natalizumab is acceptable and appropriate when considering the balance of clinical benefits and risks of this therapy.

While we are pleased that the Appraisal Consultation Document confirms our view that natalizumab is clinically effective in people with RES MS, we are disappointed that it goes on to recommend that natalizumab is not provided to people with RES MS within the NHS because it is considered not to be cost effective. We do not understand the decision made in the Appraisal Consultation Document to use best supportive care as the comparator to determine cost effectiveness in the RES group, given the clinical reality and the expert evidence presented to the committee. This comparator is completely unrealistic as all such patients will be treated with beta interferon (if not more aggressive and unlicensed drugs).

People with RES MS have frequent and disabling relapses, an active MRI scan, and a poor prognosis. Treatment with beta interferon is the currently recommended first-line standard of practice for people with RES MS, and it would not be acceptable clinical practice to offer best supportive care only to people with RES MS. The appropriate comparison for evaluating the cost effectiveness of natalizumab in RES MS should therefore be beta interferon.

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We ask you to acknowledge best current practice in treating people with RES and use beta interferon (and not best supportive care) as the comparison in analysing cost effectiveness in this group. We do hope that you will then find the cost per QALY acceptable and accordingly recommend natalizumab as a treatment that is provided in the NHS for people with RES MS.

Yours sincerely

Sent unsigned to avoid delay

Chris Allen
Chair, MS Panel, Association of British Neurologists

Members of the MS Panel with disclosures added:

Chris Allen, Consultant Neurologist, Addenbrooke's Hospital, Cambridge (Chair): no conflict of interest.

David Miller, Professor of Clinical Neurology, Institute of Neurology, University College London (ABN nominated clinical expert for this appraisal):
I have been an investigator in phase 1, 2 and 3 randomised, controlled trials of natalizumab in MS over the past decade, with a particular focus on the evaluation of MRI outcomes. My group has received research grants from the trial sponsors - Elan and Biogen Idec - for performing MRI analysis in these trials. I have received honoraria from Biogen Idec for serving on the advisory committees of these trials and for speaking at meetings. I currently serve on the advisory committee of a one-year follow on study of natalizumab treatment that is being offered to patients who were involved in the earlier randomised controlled trials. Negotiation between Biogen Idec and the Institute of Neurology is currently taking place for my research group to receive a grant to perform analysis of MRI scans in a new MS trial. My group currently receives a grant from GlaxoSmithKline for MRI analysis in another new MS trial. Agreements entered into with the companies contain confidentiality clauses.

John Zajicek, Professor, Department of Neurology, Derriford Hospital, Plymouth: I have received funding to attend educational meetings and deliver lectures sponsored by Biogen as well as Serono, Schering, and Teva.

Alan Thompson, Professor, Institute of Neurology, Queen Square, London: Declaration sent via another organisation.

Jeremy Dick
Carolyn Young
David Chadwick
Fred Schon
Christopher Martyn