

Consultant Neurologists:

Dr D A Cottrell
Dr IT Ferguson
Dr RJ Hardie
Dr P Heywood
Dr SD Lhatoo
Dr IEC Ormerod
Professor NJ Scolding
Dr KA Sieradzan
Dr A Wilkins

Department of Neurology
Frenchay Hospital
Frenchay Park Road
BRISTOL BS16 1LE

Direct Dial:
Tel.
Fax:

NJS/DHM

03 April 2007

Dr. Carole Longson,
Director, Centre for Health Technology Evaluation,
Mid City Place,
71 High Holborn,
London,
WC1V 6NA

Dear Dr. Longson,

Re: Natalizumab

Thank you for sending me the confidential Appraisal Consultation Document regarding Natalizumab for patients with multiple sclerosis. I note the overall negative conclusion, the Committee proposing not to recommend Natalizumab in either of the proposed treatment groups.

This of course is a cause for concern, and will attract considerable adverse publicity, not least when the Committee makes it clear that it has “accepted that Natalizumab is clinically effective” for at least one of the proposed therapy groups.

I have three comments to offer.

First, your draft document indicates that the manufacturer has submitted disability data to NICE but has done so stipulating that these data should not be made available to other parties. This is extremely unfortunate. Inevitably one must conclude that the data showed no useful impact on disability progression – but clarification or correction of this would be welcome.

Secondly, the conclusion concerning the “RES Group” (rapidly evolving severe disease) I suspect may be based on a flawed premise. In section 4.8, it is said that “the appropriate comparator in current UK practice is best supportive care”, and that because Natalizumab is (naturally) far more expensive than “best supportive care”, Natalizumab cannot be recommended. This is mistaken. It is my belief that the great majority of neurologists in the United Kingdom would prescribe treatment with either interferon or Copaxone to individuals with rapidly evolving severe multiple sclerosis; these individuals would not be left on no disease modifying treatments.

What is more, the defining characteristics of individuals in the RES group clearly and explicitly fall within the Guidelines for the recommended prescription of interferons or Copaxone in multiple sclerosis issued and still pertinent under the Department of Health Risk Sharing Scheme. In other words the Department of Health would recommend treating the RES group with interferons or Copaxone.

Therefore the financial comparator must surely be “treatment with current DMTs”, not “best supportive care”.

Finally, this having been said, it is the case that many specialist neurologists have been both surprised and very disappointed by the decision of the manufacturer to place such high costs on Natalizumab. I wondered if there were any opportunity in this document to make even clearer than is currently the case the fact that a significant reduction in the cost would very substantially alter the equation, so placing more responsibility and onus on the manufacturer rather than NICE itself. I suspect, however, that this is beyond your brief.

I would be very grateful indeed if the contents of this remained confidential.

With kind regards,

Yours sincerely,

Professor N J Scolding
Burden Professor of Clinical Neurosciences

CONFIDENTIAL
Professor John Zajicek,
Consultant Neurologist,
Derriford Hospital,
Derriford,
Plymouth,
PL6 8DH