

National Institute for Health and Clinical Excellence

Health Technology Appraisal

Natalizumab for the treatment of multiple sclerosis

Royal College of Nursing

Introduction

With a membership of over 395,000 registered nurses, midwives, health visitors, nursing students, health care assistants and nurse cadets, the Royal College of Nursing (RCN) is the voice of nursing across the UK and the largest professional union of nursing staff in the world. RCN members work in a variety of hospital and community settings in the NHS and the independent sector. The RCN promotes patient and nursing interests on a wide range of issues by working closely with the Government, the UK parliaments and other national and European political institutions, trade unions, professional bodies and voluntary organisations.

The RCN welcomes the opportunity to review and respond to the Appraisal Consultation Document on the use of Natalizumab for the treatment of multiple sclerosis.

Response

The preliminary recommendation from the NICE Appraisal Committee not to use Natalizumab in the treatment of patients with rapidly evolving severe multiple sclerosis is disappointing and shocking from MS Specialist Nurses' point of view.

We disagree with the assertion that best supportive care (BSC) is the most appropriate comparator for Tysabri in the RES group. This essentially means that treatment would be denied to those patients with aggressive active disease. This patient group has aggressive relapsing-remitting disease, experiencing highly active disease with frequent disabling relapses and rapidly accumulating severe disability. This will ultimately have an impact on the quality of life of the patient and their family

and will place enormous burden on hospital and community resources with regards to health and social care services.

Whilst interferon and glatiramer acetate are not generally effective in this patient group and therefore, are not used long term, this does not mean that the treatment of choice is BSC - far from it. BSC is an option only when all other therapy options have been exhausted; this is because offering best supportive care to an individual with rapidly evolving severe MS condemns them to rapid deterioration of their condition.

In practice what happens in many centres is that mitoxantrone is offered to patients in the RES group - either as first line or if high dose interferon beta is not effective.

Treatment may vary, for instance, in one practice, 15% of patients started on DMDs in the last 12 months were prescribed Mitoxantrone - however this is a toxic drug with limited time frame due to maximum dosing and potentially severe side effects including death from leukaemia and cardio toxicity - clinicians would much prefer to have the option of prescribing Tysabri which is a safer, condition specific and a potentially longer term medication.

We are pleased that NICE accepts the clinical effectiveness of Tysabri and have noted the impact on improvement of EDSS score in patients prescribed Tysabri which is unprecedented as a treatment effect in MS. We would however stress that using best supportive care as a comparator does not accurately represent clinical practice - whilst there is no licensed indication for RES MS patients at the moment, this does not mean that doing nothing is the preferred option - as clinicians we will prescribe high dose interferon beta (Betaferon or Rebif 44 at a cost of up to GBP12,000 pa) for as long as this is tolerated or having any measurable effect. Alternatively mitoxantrone will be used in many centres though with reluctance given the risk/benefits ratio of mitoxantrone. Despite the risks, clinicians use this believing it to be a preferable option to BSC. It is imperative that NICE reconsider their assumptions around the use of BSC as a comparator to determine cost effectiveness.

Conclusion

We would urge NICE to review the Appraisal Consultation Document on the use of natalizumab in rapidly evolving Multiple Sclerosis and reconsider the recommendations on clinical and ethical grounds.

April 2007

The decision that best supportive care is the most appropriate comparator for patients with rapidly evolving severe multiple sclerosis is flawed. This should be reconsidered in the light of the impact this decision will have on the management and treatment of people with MS, who desperately deserve to be treated and to have an improved quality of life.