

## Statement of Advice

### natalizumab (Tysabri®) 300 mg concentrate for solution for infusion (No: 979/14)

#### Biogen Idec Ltd

9 May 2014

**ADVICE:** in the absence of a submission from the holder of the marketing authorisation

natalizumab (Tysabri®) is not recommended for use within NHS Scotland.

**Indication under review:** single disease modifying therapy in highly active relapsing remitting multiple sclerosis (RRMS) for adult patients aged 18 years and over with high disease activity despite treatment with glatiramer acetate.

SMC has previously not recommended natalizumab for use in patients with high disease activity despite treatment with beta-interferon. The marketing authorisation has now been extended to include use in patients with high disease activity despite treatment with glatiramer. The holder of the marketing authorisation has not made a submission to SMC regarding this product in this setting. As a result we cannot recommend its use within NHSScotland.

SMC has previously accepted natalizumab (Tysabri®) for restricted use as a single disease modifying therapy in highly active RRMS in patients with rapidly evolving severe RRMS and this advice remains in place.

#### **Advice context:**

*No part of this advice may be used without the whole of the advice being quoted in full.*

*This advice represents the view of the Scottish Medicines Consortium. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.*

**Chairman,  
Scottish Medicines Consortium**