All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

Natalizumab (Tysabri®)

Biogen Idec Ltd

November 2013

Statement of Advice

In the absence of a submission from the holder of the marketing authorisation, natalizumab (Tysabri®) cannot be endorsed for use within NHS Wales as a single disease modifying therapy in highly active relapsing remitting multiple sclerosis for adult patients aged 18 years and over with high disease activity despite treatment with glatiramer acetate.

Advice context:
The All Wales Medicines Strategy Group (AWMSG) takes into account the National Institute for Health and Care Excellence (NICE) future work programme when considering whether a product will be appraised. To avoid duplication of effort, AWMSG would not normally consider undertaking an appraisal if NICE intend to publish final technology appraisal advice for the same product within twelve months of the projected Form B submission date. AWMSG advice is interim to that of NICE, should NICE subsequently publish guidance.

The above medicine cannot be endorsed for use within NHS Wales as a technology appraisal by NICE or AWMSG has not been undertaken. The medicine should NOT be prescribed routinely within NHS Wales for the indication stated above.

In the absence of guidance issued by NICE or AWMSG, clinicians should continue to exercise their clinical judgement when providing care for an individual patient. This should be in consultation with the patient and/or guardian or carer, based on the best available evidence.

This statement will be removed on receipt of a submission (i.e. the full submission [Forms A and B] or limited submission [Forms A and C]) or when final technology appraisal advice from NICE becomes available.