All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

Temozolomide intravenous solution (Temodal®)

for the treatment of gliobastoma multiforme

Merck Sharp & Dohme Ltd

September 2011

Statement of Advice

ADVICE: in the absence of a submission from the holder of the marketing authorisation, temozolomide intravenous solution (Temodal®) cannot be endorsed for use within NHS Wales for the treatment of adult patients with newly-diagnosed glioblastoma multiforme concomitantly with radiotherapy (RT) and subsequently as monotherapy treatment; children from the age of three years, adolescents and adult patients with malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy.

Advice context:
The All Wales Medicines Strategy Group (AWMSG) takes into account the National Institute for Health and Clinical 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 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 an 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 NICE guidance becomes available.