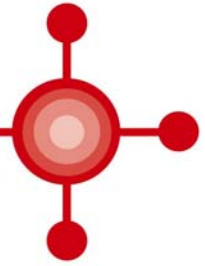


All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan



AWMSG ADVICE SUPERSEDED BY NICE GUIDANCE (TA206)

NICE GUIDANCE ISSUED OCTOBER 2010

(Refer to NICE website for full guidance on NICE recommendations,
including any specific restrictions on the use of the technology)

Bendamustine (Levact[®])

**for the treatment of indolent non-Hodgkin's lymphomas as
monotherapy in patients who have progressed during or
within 6 months following treatment with rituximab or
rituximab containing regimen**

Napp Pharmaceuticals

November 2010

Statement of Advice

ADVICE: in the absence of a submission from the holder of the marketing authorisation, bendamustine (Levact[®]) cannot be endorsed for use within NHS Wales for the treatment of indolent non-Hodgkin's lymphomas as monotherapy in patients who have progressed during or within 6 months following treatment with rituximab or rituximab containing regimen.

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 Minister for Health and Social Services has ratified that 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.