

**AWMSG ADVICE SUPERSEDED BY
NICE GUIDANCE (TA538)
NICE GUIDANCE ISSUED JULY 2018**

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

Dinutuximab beta (Qarziba[®]) Concentrate for solution for infusion

EUSA Pharma (Europe) Ltd

August 2017

Statement of Advice

In the absence of a submission from the holder of the marketing authorisation, dinutuximab beta (Dinutuximab beta Apeiron[®]) cannot be endorsed for use within NHS Wales for the treatment of high-risk neuroblastoma in patients aged 12 months and above, who have previously received induction chemotherapy and achieved at least a partial response, followed by myeloablative therapy and stem cell transplantation, as well as patients with history of relapsed or refractory neuroblastoma, with or without residual disease. Prior to the treatment of relapsed neuroblastoma, any actively progressing disease should be stabilised by other suitable measures. In patients with a history of relapsed/refractory disease and in patients who have not achieved a complete response after first line therapy, Dinutuximab beta Apeiron[®] should be combined with interleukin 2 (IL 2).

Marketing authorisation holder on first issue:	EUSA Pharma (Europe) Ltd
Date of first issue	August 2017
Last reviewed	August 2018
Review changes	Trade name changed from Dinutuximab beta Apeiron [®] to Qarziba [®]

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 intends to publish final technology appraisal guidance (STA/MTA/HST) for the same product and indication(s) within 12 months of the date of marketing authorisation. AWMSG guidance 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 updated when final NICE technology appraisal guidance becomes available.