All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

AWMSG ADVICE SUPERSEDED BY NICE GUIDANCE (TA423 AND TA515)

NICE GUIDANCE ISSUED DECEMBER 2016 AND FEBRUARY 2018

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

Final Appraisal Recommendation

Advice No: 0916 – April 2016

Eribulin mesilate (Halaven®▼) 0.44 mg/ml solution for injection

Submission by Eisai Ltd

Recommendation of AWMSG

Eribulin mesilate (Halaven®▼) is licensed for the treatment of adult patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting unless patients were not suitable for these treatments.

Eribulin mesilate (Halaven®▼) is recommended as an option for restricted use within NHS Wales after at least two prior chemotherapeutic regimens for advanced disease which includes capecitabine.

This recommendation applies only in circumstances where the approved Wales Patient Access Scheme (WPAS) is utilised or where the list/contract price is equivalent or lower than the WPAS price.

Eribulin mesilate (Halaven®▼) is not recommended for use within NHS Wales outside of these circumstances.

Additional note(s):

- The company submission provided evidence of the clinical and cost-effectiveness of eribulin mesilate (Halaven®▼) within a subpopulation of patients (after at least two prior chemotherapeutic regimens, post-capecitabine) within the licensed indication.
- AWMSG considered that eribulin mesilate (Halaven®▼) satisfied the AWMSG criteria for appraising orphan and ultra-orphan medicines and medicines developed specifically for rare diseases.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 1212), which includes the AWMSG Secretariat Assessment Report (ASAR), the Preliminary Appraisal Recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.

This recommendation has been ratified by the Minister for Health and Social Services and will be considered for review every three years.