All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

AWMSG ADVICE SUPERSEDED BY NICE GUIDANCE (TA488)

NICE GUIDANCE ISSUED NOVEMBER 2017

(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: 1915 – June 2015

Regorafenib (Stivarga®▼) 40 mg film-coated tablets

Submission by Bayer Healthcare Pharmaceuticals

Recommendation of AWMSG

Regorafenib (Stivarga®▼) is recommended for use within NHS Wales for the treatment of adult patients with unresectable or metastatic gastrointestinal stromal tumours (GIST) who progressed on or are intolerant to prior treatment with imatinib and sunitinib.

This recommendation applies only in circumstances where the approved Wales Patient Access Scheme is utilised.

Additional note:

- Please refer to the Summary of Product Characteristics for the full licensed indication.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 1018), 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.