All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

Final Appraisal Recommendation

Advice No: 2515 – September 2015

Riociguat (Adempas®)
0.5 mg, 1 mg, 1.5 mg, 2 mg and 2.5 mg film-coated tablets

Submission by Bayer Healthcare Pharmaceuticals

Recommendation of AWMSG

Riociguat (Adempas®) is recommended as an option for restricted use within NHS Wales for the treatment of adult patients with pulmonary arterial hypertension (PAH) with WHO functional class II to III to improve exercise capacity. This recommendation applies only in circumstances where the approved Wales Patient Access Scheme is utilised.

Riociguat (Adempas®) should be restricted for use as a PAH-specific monotherapy as an alternative treatment option to endothelin receptor antagonist (ERA) monotherapy in adult patients with PAH of WHO functional class II to III.

Riociguat (Adempas®) is not recommended for use within NHS Wales outside of this subpopulation.

Additional note(s):

- Please refer to the Summary of Product Characteristics for the full licensed indication.
- The use of riociguat (Adempas®) should be directed by a physician experienced in the treatment of PAH at one of the National Commissioning Group (NCG) centres across the UK.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 558), 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 Welsh Government and will be considered for review every three years.

Marketing authorisation holder on first issue	Bayer Healthcare Pharmaceuticals
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