Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group

Final Appraisal Recommendation

Advice No: 1120 – October 2020

Meropenem/vaborbactam (Vaborem®) 1 g/1 g powder for concentrate for solution for infusion

Submission by Menarini International Operations Luxembourg S.A.

Recommendation of AWMSG

Meropenem/vaborbactam (Vaborem®) is recommended as an option for restricted use within NHS Wales.

Meropenem/vaborbactam (Vaborem®) is licensed for the treatment of complicated urinary tract infection (cUTI) including acute pyelonephritis (AP), complicated intra-abdominal infection (cIAI), hospital-acquired pneumonia (HAP) including ventilator associated pneumonia (VAP) in adults; and for the treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above. Meropenem/vaborbactam is also indicated for the treatment of infections due to aerobic Gram-negative organisms in adults with limited treatment options.

Meropenem/vaborbactam (Vaborem®) is restricted for use in the sub-population of adult patients with confirmed carbapenem-resistant Enterobacteriaceae-*Klebsiella pneumoniae* carbapenemase (CRE-KPC) associated infections.

Meropenem/vaborbactam (Vaborem®) 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
- Meropenem/vaborbactam (Vaborem®) is appropriate for specialist only prescribing on the advice of a Consultant Microbiologist or Infectious Disease Consultant

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 2760), 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.