

<b>Title</b>	VABOREM – A Health Technology Assessment
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<b>Reference</b>	link to full report in French <a href="https://www.has-sante.fr/jcms/p_3153000/fr/vaborem">https://www.has-sante.fr/jcms/p_3153000/fr/vaborem</a>

### Aim

Assessment of VABOREM (meropenem/vaborbactam) with a view to funding by the French national health insurance system and of its clinical contribution compared to other strategies in the treatment of the following infections:

- complicated urinary tract infections, including pyelonephritis;
- complicated intra-abdominal infections;
- hospital-acquired pneumonia, including ventilator-associated pneumonia.

Treatment of patients with associated bacteremia, or suspected to be associated with one of the infections listed above.

VABOREM is also indicated in the treatment of infections caused by Gram-negative aerobic bacteria in adult patients whose therapeutic options are limited.

### Conclusions of Transparency Committee

- The infections treated with this medicinal product are life-threatening to the patient, either immediately or as a result of complications.
- It is a curative treatment.
- The efficacy/adverse effects ratio is high.
- There are few therapeutic alternatives.
- It is a last-resort treatment.
- VABOREM is likely to have an impact on public health.

Considering these elements, the Committee deems that the clinical benefit of VABOREM in the MA indications is:

- substantial only as a last resort for the treatment of patients with enterobacteria infections susceptible to the meropenem/vaborbactam combination and for whom recourse to other beta-lactams and carbapenems (meropenem or imipenem-cilastatin) cannot be envisaged in the event of resistance, in particular via the production of KPC-type carbapenemase;
- insufficient to justify its funding by the French national health insurance system in all other clinical situations.

### Considering:

its *in vitro* activity on Extended-Spectrum Beta-Lactamase-Producing Enterobacteriaceae (ESBL-PE), particularly KPC type,

- experience acquired with meropenem, a carbapenem widely used in the treatment of severe nosocomial infections due to Gram-negative bacteria,
- the demonstrated efficacy of the meropenem/vaborbactam combination in moderate to mild complicated urinary tract infections (including pyelonephritis),
- limited clinical data (TANGO II study) suggesting high efficacy in patients with carbapenem-resistant enterobacteria infections (CRE), primarily via the production of KPC-type carbapenemase,
- the fact that the meropenem/vaborbactam combination is one of the few current antibiotics active on certain carbapenemase-producing enterobacteria, VABOREM provides moderate clinical added value (CAV III) in the treatment of enterobacteria infections susceptible to the meropenem/vaborbactam combination and for whom recourse to other beta-lactams and carbapenems (meropenem or imipenem-cilastatin) cannot be envisaged in the event of resistance.

### Recommendations

The Transparency Committee issued its approval for the funding of VABOREM by the French national health insurance system in the MA indication only as a last resort for the treatment of patients with enterobacteria infections susceptible to the meropenem/vaborbactam combination and for whom recourse to other beta-lactams and carbapenems (meropenem or imipenem-cilastatin) cannot be envisaged in the event of resistance, in particular via the production of KPC-type carbapenemase.

### Methods

The assessment of VABOREM was founded on evidence-based medicine with a critical analysis of the clinical data.

### Written by

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